Instructions – Identify the generic product type by providing the FDA Product Classification Regulation number under which the product is classified. The definitions for each product classification may be found in Title 21 of the Code of Federal Regulations in Sections 862 through 892 and on the FDA web site at <a href="http://www.fda.gov/cdrh/yr2000/classification.html">http://www.fda.gov/cdrh/yr2000/classification.html</a>. For products that have not been classified by the FDA, provide a description of the generic product type, not a manufacturer-specific trade or brand name. Enter the appropriate classification number or name on Line #5 of <a href="Compliant Products - FORM">Compliant Products - FORM</a> FDA 3474.

Product Classification Name (Identify the generic product type under which the product being reported on Compliant Products – FORM FDA 3474 is classified.)	FDA Classification Regulation Number (Enter the associated CFR number on Line #5 of Compliant Products – FORM FDA 3474.)
CLINICAL CHEMISTRY AND CLINICAL TOXI	COLOGY DEVICES – PART 862
Acid phosphatase (total or prostatic) test system.	862.1020
Adrenocorticotropic hormone (ACTH) test system.	862.1025
Alanine amino transferase (ALT/SGPT) test system.	862.1030
Albumin test system.	862.1035
Aldolase test system.	862.1040
Aldosterone test system.	862.1045
Alkaline phosphatase or isoenzymes test system.	862.1050
Delta-aminolevulinic acid test system.	862.1060
Ammonia test system.	862.1065
Amylase test system.	862.1070
Androstendedione test system.	862.1075
Androsterone test system.	862.1080
Angiotensin I and renin test system.	862.1085
Angiotensin converting enzyme (A.C.E.) test system.	862.1090
Ascorbic acid test system.	862.1095
Aspartate amino transferase (AST-SGOT) test system.	862.1100
Bilirubin (toal or direct) test system.	862.1110
Bilirubin (total and unbound) in the neonate test system.	862.1113
Urinary bilirubin and its conjugates (nonquantitative) test	862.1115
Blood gases (Pco2Po2) and blood pH test system.	862.1120
Blood volume test system.	862.1130
C-peptides of proisulin test system.	862.1135
Calcitonin test system.	862.1140
Calcium test system.	862.1145
Calibrator.	862.1150
Human chorionic gonadotropin (HCG) test system.	862.1155
Bicarbonate/carbon dioxide test system.	862.1160
Catecholamines (total) test system.	862.1165
Chloride test system.	862.1170
Cholesterol (total) test system.	862.1175
Cholylglycine test system.	862.1177
Chymotrypsin test system.	862.1180
Compound S (11-deoxycortisol) test system.	862.1185
Cojugated sulfolithocholic acid (SLCG) test system.	862.1187
Copper test system.	862.1190
Corticoids test system.	862.1195
Corticosterone test system.	862.1200
Cortisol (hydrocortisone and hydroxycorticosterone) test	862.1205
Creatine test system.	862.1210

Product Classification Name	FDA Classification Regulation Number
(Identify the generic product type under which the product being reported on <b>Compliant Products – FORM FDA 3474</b> is classified.)	
Creatine phosphokinase/creatine kinase or isoenzymes test	862.1215
Creatine test system.	862.1225
Cyclic AMP test system.	862.1230
Cystine test system.	862.1240
Dehydroeplandrosterone (free and sulfate) test system.	862.1245
Desoxycorticosterone test system.	862.1250
2,3-Diphosphoglyceric acid test system.	862.1255
Estradiol test system.	862.1260
Estriol test system.	862.1265
Estrogens (total, in pregnancy) test system.	862.1270
Estrogens (total, nonpregnancy) test system.	862.1275
Estrone test system.	862.1280
Etiocholanolone test system	862.1285
Fatty acids test system.	862.1290
Folic acid test system.	862.1295
Follicle-stimulating hormone test system.	862.1300
Formiminoglutamic acid (FIGLU) test system.	862.1305
Galactose test system.	862.1310
Galactose-1-phosphate uridyl transferase test system.	862.1315
Gastric acidity test system.	862.1320
Gastrin test system	862.1325
Globulin test system.	862.1330
Glucagon test system.	862.1335
Urinary glucose (nonquantitative) test system.	862.1340
Glucose test system.	862.1345
Gamma-glutamyl transpeptidase and isoenzymes test	862.1360
Glucathione test system.	862.1365
Human growth hormone test system.	862.1370
Histidine test system.	862.1375
Urinary homocystine (nonquantitative) test system.	862.1377
Hydroxybutyric dehydrogenase test system.	862.1380
17-Hydroxycorticosteroids (17-ketogenic steroids) test	862.1385
5-Hydroxyindole acetic acid/serotonin test system.	862.1390
17-Hydroxyprogesterone test system.	862.1395
Hydroxyproline test system.	862.1400
Immunoreactive insulin test system.	862.1405
Iron (non-heme) test system.	862.1410
Iron-binding capacity test system.	862.1415
Isocitric dehydrogenase test system.	862.1420
17-Ketosteroids test system.	862.1430
Ketones (nonquantitative) test system.	862.1435
Lactate dehydrogenase test system.	862.1440
Lactate dehydrogenase ixoenzymes test system.	862.1445
Lactic acid test system.	862.1450
Lecithin/sphingomyelin ratio in amniotic fluid test system.	862.1455
Leucine aminopeptidase test system.	862.1460
Lipase test system.	862.1465
Lipid (total) test system.	862.1470
zipia (totai) test system.	Code of Endoral Pagulations April 1 1009

Product Classification Name	FDA Classification Regulation Number
(Identify the generic product type under which the product being reported on <b>Compliant Products – FORM FDA 3474</b> is classified.)	(Enter the associated CFR number on Line #5 of Compliant Products – FORM FDA 3474.)
Lipoprotein test system.	862.1475
Luteinizing hormone test system.	862.1485
Lysozyme (muramidase) test system.	862.1490
Magnesium test system.	862.1495
Malic dehydrogenase test system.	862.1500
Mucopolysaccharides (nonquantitative) test system.	862.1505
Methylmalonic acid (nonquantitative) test system.	862.1509
Nitrite (nonquantitative) test system.	862.1510
Nitrogen (amino-nitrogen) test system.	862.1515
5'-Nucleotidase test system.	862.1520
Plasma oncometry test system.	862.1530
Ornithine carbamyl transferase test system.	862.1535
Osmolality test system.	862.1540
Oxalate test system.	862.1542
Parathyroid hormone test system.	862.1545
Urinary pH (nonquantitative) test system.	862.1550
Phenylalanine test system.	862.1555
Urinary phenylketones (non-quantitative) test system.	862.1560
6-Phosphogluconate dehydrogenase test system.	862.1565
Phosphohexose isomerase test system.	862.1570
Phospholipid test system.	862.1575
Phosphorus (inorganic) test system.	862.1580
Human placental lactogen test system.	862.1585
Porphobilinogen test system.	862.1590
Porphyrins test system.	862.1595
Potassium test system.	862.1600
Pregnanediol test system.	862.1605
Pregnanetroil test system.	862.1610
Pregnenolone test system.	862.1615
Progesterone test system.	862.1620
Prolactin (lactogen) test system.	862.1625
Protein (fractionation) test system.	862.1630
Total protein test system.	862.1635
Protein-bound iodine test system.	862.1640
Urinary protein or albumin (non-quantitative) test system.	862.1645
Pyruvate kinase test system.	862.1650
Pyruvic acid test system.	862.1655
Quality control material (assayed and unassayed).	862.1660
Sodium test system.	862.1665
Sorbitol dehydrogenase test system.	862.1670
Blood specimen collection device.	862.1675
Testosterone test system.	862.1680
Thyroxine-binding globulin test system.	862.1685
Thyroid-stimulating hormone test system.	862.1690
Free thyroxine test system.	862.1695
Triose phosphate isomerase test system.	862.1700
Tryglyceride test system.	862.1705
Total triiodothyronine test system.	862.1710
Total thiodothyronine test system.	Code of Enderal Pagulations April 1 1009

Product Classification Name (Identify the generic product type under which the product being reported on Compliant Products – FORM FDA 3474 is classified.)	FDA Classification Regulation Number (Enter the associated CFR number on Line #5 of Compliant Products – FORM FDA 3474.)
Triiodothyronine uptake test system.	862.1715
Triose phosphate isomerase test system.	862.1720
Trypsin test system.	862.1725
Free tyrosine test system.	862.1730
Urea nitrogen test system.	862.1770
Uric acid test system	862.1775
Urinary calculi (stones) test system.	862.1780
Urinary urobilinogen (nonquantitative) test system.	862.1785
Uroporphyrin test system.	862.1790
Vanilmandelic acid test system.	862.1795
Vitamin A test system.	862.1805
Vitamin B12 test system.	862.1810
Vitamin E test system.	862.1815
Xylose test system.	862.1820
General purpose laboratory equipment labeled or promoted	862.2050
Calculator/data processing module for clinical use	862.2100
Centrifugal chemistry analyzer for clinical use.	862.2140
Continuous flow sequential multiple chemistry analyzer for	862.2150
Discrete photometric chemistry analyzer for clinical use.	862.2160
Micro chemistry analyzer for clinical use.	862.2170
Chromatographic separation material for clinical use.	862.2230
Gas liquid chromatography system for clinical use.	862.2250
High pressure liquid chromatography system for clinical use.	862.2260
Thin-layer chromatography system for clinical use.	862.2270
Chlorimeter, photometer, or spectrophotometer for clinical	862.2300
Clinical sample concentrator.	862.2310
Beta or gamma counter for clinical use.	862.2320
Densitometer/scanner (integrating, reflectance, TLC, or	862.2400
Electrophoresis apparatus for clinical use.	862.2485
Enzyme analyzer for clinical use.	862.2500
Flame emission photometer for clinical use.	862.2540
Fluorometer for clinical use.	862.2560
Microtitrator for clinical use.	862.2680
Nephelometer for clinical use.	862.2700
Plasma oncometer for clinical use.	862.2720
Pipetting and diluting system for clinical use.	862.2750
Refractometer for clinical use.	862.2800
Atomic absorption spectrophotometer for clinical use.	862.2850
Mass spectrometer for clinical use.	862.2860
Automated urinalysis system.	862.2900
Plasma viscometer for clinical use.	862.2920
Acetaminophen test system.	862.3030
Amikacin test system.	862.3035
Alcohol test system.	862.3040
Breath-alcohol test system.	862.3050
Amphetamine test system.	862.3100
Antimony test system.	862.3110
Arsenic test system.	862.3120
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Product Classification Name (Identify the generic product type under which the product being reported on Compliant Products – FORM FDA 3474 is classified.)	FDA Classification Regulation Number (Enter the associated CFR number on Line #5 of Compliant Products – FORM FDA 3474.)
Barbiturate test system.	862.3150
Benzodiazepine test system.	862.3170
Clinical toxicology calibrator.	862.3200
Carbon monoxide test system.	862.3220
Cholinesterase test system.	862.3240
Cocaine and cocainemetabolite test system.	862.3250
Codeine test system.	862.3270
Clinical toxicology control material.	862.3280
Digitoxin test system.	862.3300
Digoxin test system.	862.3320
Diphenylhydantion test system.	862.3350
Ethosuximide test system.	862.3380
Gentamicin test system	862.3450
Kanamycin test system.	862.3520
Lead test system.	862.3550
Lidocaine test system.	862.3555
Lithium test system.	862.3560
Lysergic acid diethylamide (LSD) test system	862.3580
Mercury test system.	862.3600
Methamphetamine test system	862.3610
Methadone test system.	862.3620
Methaqualone test system.	862.3630
Morphine test system.	862.3640
Neuroleptic drugs radioreceptor assay test system.	862.3645
Opiate test system.	862.3650
Phenobarbital test system.	862.3660
Phenothiazine test system.	862.3670
Primidone test system	862.3680
Propoxyphene test system.	862.3700
Quinine test system.	862.3750
Salicylate test system.	862.3830
Sulfonamide test system.	862.3850
Cannabinoid test system	862.3870
Theopylline test system.	862.3880
Tobramycin test system.	862.3900
Tricyclic antidepressant drugs test system.	862.3910
Vancomycin test system.	862.3950

Product Classification Name	FDA Classification Regulation Number
(Identify the generic product type under which the product being reported on <u>Compliant Products – FORM FDA 3474</u> is classified.)	(Enter the associated CFR number on Line #5 of Compliant Products – FORM FDA 3474.)
HEMATOLOGY AND PATHOLOGY	-
Dye and chemical solution stains.	864.1850
Synthetic cell and tissue culture media and components	864.2220
Cell and tissue culture supplies and equipment.	864.2240
Chromosome culture kit.	864.2260
Cultured animal and human cells.	864.2280
Mycoplasma detection media and components.	864.2360
Animal and human sera.	864.2800
Balanced salt solutions or formulations.	864.2875
Tissue processing equipment.	864.3010
Specimen transport and storage container	864.3250
Cytocentrifuge.	864.3300
Device for sealing microsections.	864.3400
Microscopes and accessories.	864.3600
Automated slide stainer.	864.3800
Automated tissue processor.	864.3875
General purpose reagent.	864.4010
Enzyme preparations.	864.4400
Automated cell counter.	864.5200
Automated differential cell counter.	864.5220
Automated blood cell diluting apparatus.	864.5240
Automated call-locating device.	864.5260
Red cell indices device.	864.5300
Microsedimentation centrifuge	864.5350
Coagulation instrument.	864.5400
	864.5425
Multipurpose system for in vitro coagulation studies.  Automated hematocrit instrument.	864.5600
	864.5620
Automated hemoglobin system.	
Automated heparin analyzer.	864.5680
Automated platelet aggregation system.	864.5700
Automated sedimentation rate device.	864.5800
Automated slide spinner.	864.5850
Blood volume measuring device.	864.5950
Bleeding time device.	864.6100
Capillary blood collection tube.	864.6150
Manual blood cell counting device.	864.6160
Hematocrit measureing device.	864.6400
Occult blood test	864.6550
Osmotic fragility test.	864.6600
Platelet adhesion test.	864.6650
Platelet aggregometer.	864.6675
Erythrocyte sedimentation rate test.	864.6700
Adenosine triphosphate release assay.	864.7040
Antithrombin III assay.	864.7060
Red blood cell enzyme assay.	864.7100
Activated whole blood clotting time tests.	864.7140
Erythropoietin assay.	864.7250

Product Classification Name	FDA Classification Regulation Number
(Identify the generic product type under which the product being reported on <u>Compliant Products – FORM FDA 3474</u> is classified.)	(Enter the associated CFR number on Line #5 of Compliant Products – FORM FDA 3474.)
Euglobulin time assay.	864.7275
Factor deficiency test.	864.7290
Fibrin monomer paracoagulation test.	864.7300
Fibrinogen/fibrin degradation products assay.	864.7320
Fibrinogen determination system.	864.7340
Erthrocytic glucose-6-phosphate dehydrogenase assay.	864.7360
Glutathione reductase assay.	864.7375
Hemoglobin A2 assay.	864.7400
Abnormal hemoglobin assay.	864.7415
Carboxyhemoglobin assay.	864.7425
Electrophoretic hemoglobin analysis system.	864.7440
Fetal hemoglobin assay.	864.7455
Glyosylated hemoglobin assay.	864.7470
Sulfhemoglobin assay.	864.7490
Whole blood hemoglobin assays.	864.7500
Heparin assay.	864.7525
Leukocyte alkaline phosphatase test.	864.7660
Leukocyte peroxidase test.	864.7675
Platelet factor 4 radioimmunoassay.	864.7695
Prothrombin consumption test.	864.7720
Prothrombin-proconvertin test and thrombotest.	864.7735
Prothrombin time test.	864.7750
Sickle cell test.	864.7825
Thrombin time test.	864.7875
Thromboplastin generation test.	864.7900
Partial thromboplastin time tests.	864.7925
Bothrops atrox reagent.	864.8100
Calibrator for cell indices.	864.8150
Calibrator for hemoglobin or hematocrit measurement.	864.8165
Calibrator for platelet counting.	864.8175
Calibrator for red cell and white cell counting.	864.8185
Blood cell diluent.	864.8200
Lymphocyte separation medium.	864.8500
Red cell lysing reagent.	864.8540
Hematology quality control mixture.	864.8625
Russell viper venom reagent.	864.8950
Blood bank supplies.	864.9050
	864.9100
Empty container for the collection and processing of blood	
Vacuum-assisted blood collection system.	864.9125
Processing system for frozen blood.	864.9145
Blood group substances of nonhuman origin for in vitro	864.9160
Automated blood grouping and antibody test system.	864.9175
Blood grouping view box.	864.9185
Blood mixing devices and blood weighing devices.	864.9195
Blood and plasma warming device.	864.9205
Cell-freezing apparatus and reagents for in vitro diagnostic	864.9225
Automated blood cell separator.	864.9245
Blood bank centrifuge for in vitro diagnostic use.	864.9275

Product Classification Name (Identify the generic product type under which the product being reported on Compliant Products – FORM FDA 3474 is classified.)	FDA Classification Regulation Number (Enter the associated CFR number on Line #5 of Compliant Products – FORM FDA 3474.)
Automated cell-washing centrifuge for immuno-hematology.	864.9285
Automated Coombs test system.	864.9300
Copper sulfate solution for specific gravity determinations.	864.9320
Stabilized enzyme solution.	864.9400
Lectins and protectins.	864.9550
Environmental chamber for storage of platelet concentrate.	864.9575
Potentiating media for in vitro diagnostic use.	864.9600
Quality control kit for blood banking reagents.	864.9650
Blood storage refrigerator and blood storage freezer.	864.9700
Heat-sealing device.	864.9750
Transfer set.	864.9875

Product Classification Name (Identify the generic product type under which the product being reported on Compliant Products – FORM FDA 3474 is classified.)	FDA Classification Regulation Number (Enter the associated CFR number on Line #5 of Compliant Products – FORM FDA 3474.)
IMMUNOLOGY AND MICROBIOLOGY	DEVICES – PART 866
Antimicrobial susceptibility test disc.	866.1620
Antimicrobial susceptibility test powder.	866.1640
Culture medium for antimicrobial susceptibility tests.	866.1700
Staphylococcal typing bacteriophage.	866.2050
Anaerobic chamber.	866.2120
Coagulase plasma.	866.2160
Automated colony counter.	866.2170
Manual colony counter.	866.2180
Multipurpose culture medium.	866.2300
Differential culture medium.	866.2320
Enriched culture medium.	866.2330
Microbiological assay culture medium.	866.2350
Selective culture medium.	866.2360
Transport culture medium.	866.2390
Culture medium for pathogenic Neisseria spp.	866.2410
Oxidase screening test for gonorrhea.	866.2420
Automated medium dispensing and stacking device.	866.2440
Supplement for culture media.	866.2450
Quality control kit for culture media.	866.2480
Microtiter diluting and dispensing device.	866.2500
Microbiological incubator.	866.2540
Microbial growth monitor.	866.2560
Gas-generating devive.	866.2580
Wood's fluorescent lamp.	866.2600
Microorganism differentiation and identification device.	866.2660
Automated zone reader.	866.2850
Microbiological specimen collection and transport device	866.2900
Acinetobacter calcoaceticus serological reagents.	866.3010
Adenovirus serological reagents.	866.3020
Arizona spp. serological reagents.	866.3035
Aspergillus spp. serological reagents.	866.3040
Blastomyces dermatitidis serological reagents.	866.3060
Bordetella spp. serological reagents.	866.3065
Brucella spp. serological reagents.	866.3085
Campylobacter fetus serological reagents.	866.3110
Chlamydia serological reagents.	866.3120
Citrobacter spp. serological reagents.	866.3125
Coccidioides immitis serological reagents.	866.3135
Corynebacterium spp. serological reagents.	866.3140
Coxsackievirus serological reagents.	866.3145
Cryptococcus neoformans serological reagents.	866.3165
Cytomegalovirus serological reagents.	866.3175
Echinococcus spp. serological reagents.	866.3200
Echovirus serological reagents.	866.3205
Entamoeba histolytica serological reagents.	866.3220
Epstein-Barr virus serological reagents.	866.3235

Product Classification Name	FDA Classification Regulation Number
(Identify the generic product type under which the product being reported on Compliant Products – FORM FDA 3474 is classified.)	(Enter the associated CFR number on Line #5 of Compliant Products – FORM FDA 3474.)
Equine encephalomyelitis virus serological reagents.	866.3240
Erysipelothrix rhusiopathiae serological reagents.	866.3250
Escherichia coli serological reagents.	866.3255
Flavobacterium spp. serological reagents.	866.3270
Francisella tularensis serological reagents.	866.3280
Gonococcal antibody test (GAT).	866.3290
Haemophilus spp. serological reagents.	866.3300
Herpes simplex virus serological reagents.	866.3305
Histoplasma capsulatum serological reagents.	866.3320
Influenza virus serological reagents.	866.3330
Klebsiellal spp. serological reagents.	866.3340
Leptospira spp. serological reagents.	866.3350
Listeria spp. serological reagents.	866.3355
Lymphocytic choriomeningitis virus serological reagents.	866.3360
Mycobacterium tuberculosis immunofluorescent reagents.	866.3370
Mycoplasma spp. serological reagents.	866.3375
Mumps virus serological reagents.	866.3380
Neisseria spp. direct serological test reagents.	866.3390
Parainfluenza virus serological reagents	866.3400
Poliovirus serological reagents.	866.3405
Proteus spp. (Weil-Felix) serological reagents.	866.3410
Pseudomonas spp. serological reagents.	866.3415
Rabiesvirus immunofluorescent reagents.	866.3460
Reovirus serological reagents.	866.3470
Respiratory syncytial virus serological reagents.	866.3480
Rhinovirus serological reagents.	866.3490
Rickettsia serological reagents.	866.3500
Rubella virus serological reagents.	866.3510
Rubeola (measles) virus serological reagents.	866.3520
Serratia spp. serological reagents.	866.3550
Schistosoma spp. serological reagents.	866.3600
Serratia spp. serological reagents.	866.3630
Shigella spp. serological reagents.	866.3660
Sporothrix schenckii serological reagents.	866.3680
Staphylococcus aureus serological reagents.	866.3700
Streptococcus spp. exoenzyme reagents.	866.3720
Streptococcus spp. serological reagents.	866.3740
Toxoplasma gondii serologicalk reagents.	866.3780
Treponema pallidum nontreponemal test reagents.	866.3820
Treponema pallidum treponemal test reagents	866.3830
Trichinella spiralis serological reagents.	866.3850
Trypanosoma spp. serological reagents	866.3870
Varicella-zoster virus serological reagents.	866.3900
Vibrio cholerae serological reagents.	866.3930
Complement reagent.	866.4100
Immunoelectrophoresis equipment.	866.4500
Immunofluorometer equipment.	866.4520
Immunonephelometer equipment.	866.4540
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Product Classification Name	FDA Classification Regulation Number
(Identify the generic product type under which the product being reported on Compliant Products – FORM FDA 3474 is classified.)	(Enter the associated CFR number on Line #5 of Compliant Products – FORM FDA 3474.)
Ouchterlony agar plate.	866.4600
Radial immunodiffusion plate.	866.4800
Rocket immunoelectrophoresis equipment.	866.4830
Support gel.	866.4900
Albumin immunological test system.	866.5040
Prealbumin immunological test system.	866.5060
Human allotypic marker immunological test system.	866.5065
Alpha-1-antichymotrypsin immunological test system.	866.5080
Antimitochondrial antibody immunological test system.	866.5090
Antinuclear antibody immunological test system.	866.5100
Antiparietal antibody immunological test system.	866.5110
Antismooth muscle antibody immunological test system.	866.5120
Alpha-1-antitrypsin immunological test system.	866.5130
Bence-Jones proteins immunological test system.	866.5150
Beta-globulin immunological test system.	866.5160
Breast milk immunological test system.	866.5170
Carbonic anhydrase B and C immunological test system.	866.5200
Ceruloplasmin immunological test system.	866.5210
Cohn fraction II immunological test system.	866.5220
Colostrum immunological test system.	866.5230
Complement components immunological test system.	866.5240
Complement C1 inhibitor (inactivator) immunological test	866.5250
Complement C3b inactivator immunological test system.	866.5260
C-reactive protein immunological test system.	866.5270
Properidin factor B immunological test system.	866.5320
Factor XIII, A, S, immunological test system.	866.5330
Ferritin immunological test system.	866.5340
Fibrinopeptide A immunological test system.	866.5350
Cohn fraction IV immunological test system.	866.5360
Cohn fraction V immunological test system	866.5370
Free secretory component immunological test system	866.5380
Alpha-globulin immunological test system.	866.5400
Alpha-1-glycoproteins immunological test system.	866.5420
Alpha-2-glycoproteins immunological test system.	866.5425
Beta-2-glycoprotein I immunological test system.	866.5430
Beta-2-glycoprotein III immunological test system.	866.5440
Haptoglobin immunological test system.	866.5460
Hemoglobin immunological test system.	866.5470
Hemopexin immunological test system.	866.5490
Hypersensitivity pneumonitis immunological test system.	866.5500
Immunoglobulins A, G, M, D, and E immunological test	866.5510
Immunoglobulin G (Fab fragment specific) immunological test	866.5520
Immunoglobulin G (Fc fragment specific) immunological test	866.5530
Immunoglobulin G (Fd fragment specific) immunological test	866.5540
Immunologlobulin (light chain specific) immunological test	866.5550
Lactic dehdrogenase immunological test system.	866.5560
Lactoferrin immunological test system.	866.5570
Alpha-1-lipoprotein immunological test system.	866.5580
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Product Classification Name (Identify the generic product type under which the product being reported on <u>Compliant Products – FORM FDA 3474</u> is classified.)	FDA Classification Regulation Number (Enter the associated CFR number on Line #5 of Compliant Products – FORM FDA 3474.)
Lipoprotein X immunological test system.	866.5590
Low-density lipoprotein immunological test system.	866.5600
Alpha-2-macroglobulin immunological test system.	866.5620
Beta-2-microglobulin immunological test system.	866.5630
Infectious mononucleosis immunological test system.	866.5640
Multiple autoantibodies immunological test system.	866.5660
Myoglobin immunological test system.	866.5680
Whole human plasma or serum immunological test system.	866.5700
Plasminogen immunological test system.	866.5715
Prothrombin immunological test system.	866.5735
Radioallergosorbent (RAST) immunological test system.	866.5750
Retinol-binding protein immunological test system.	866.5765
Rheumatoid factor immunological test system.	866.5775
Seminal fluid (sperm) immunological test system.	866.5800
Systemic lupus erythematosus immunological test system.	866.5820
Total spinal fluid immunological test system.	866.5860
Thyroid autoantibody immunological test system.	866.5870
Transferrin immunological test system.	866.5880
Inter-alpha trypsin inhibitor immunological test system.	866.5890
Tumor-associated antigen immunological test system.	866.6010

Product Classification Name	FDA Classification Regulation Number
(Identify the generic product type under which the product being reported on Compliant Products – FORM FDA 3474 is classified.)	(Enter the associated CFR number on Line #5 of Compliant Products – FORM FDA 3474.)
ANESTHESIOLOGY DEVIC	
Manual algesimeter.	868.1030
Powered algesimeter.	868.1040
Argon gas analyzer.	868.1075
Arterial blood sampling kit.	868.1100
Indwelling blood oxyhemoglobin concentration analyzer.	868.1120
Indwelling blood carbon dioxide partial pressure (PC02)	868.1150
Indwelling blood hydrogen ion concentration (pH) analyzer.	868.1170
Indwelling blood oxygen partial pressure (PO2) analyzer.	868.1200
Carbon dioxide gas analyzer.	868.1400
Carbon monoxide gas analyzer.	868.1430
Enflurane gas analyzer.	868.1500
Gas collection vessel.	868.1575
	868.1620
Halothane gas analyzer.	
Helium gas analyzer.	868.1640
Neon gas analyzer.	868.1670
Nitrogen gas analyzer.	868.1690
Nitrous oxide gas analyze	868.1700
Oxygen gas analyzer.	868.1720
Oxygen uptake computer.	868.1730
Pressure plethysmograph.	868.1750
Volume plethysmograph.	868.1760
Inspiratory airway pressure meter.	868.1780
Rhinoanemometer.	868.1800
Diagnostic spirometer.	868.1840
Monitoring spirometer.	868.1850
Peak-flow meter for spirometry.	868.1860
Gas volume calibrator.	868.1870
Pulmonary-function data calculator.	868.1880
Predictive pulmonary-function value calculator.	868.1890
Diagnostic pulmonary-function interpretation calculator.	868.1900
Esophageal stethoscope.	868.1910
Esophageal stethoscope with electrical conductors.	868.1920
Stethoscope head.	868.1930
Switching valve (ploss).	868.1965
Water vapor analyzer	868.1975
Ultrasonic air embolism monitor.	868.2025
Bourdon gauge flowmeter.	868.2300
Uncompensated thorpe tube flowmeter.	868.2320
Compensated thorpe tube flowmeter.	868.2340
Gas calibration flowmeter.	868.2350
Breathing frequency monitor.	868.2375
Lung water monitor.	868.2450
Cutaneous carbon dioxide (PCCO2) monitor.	868.2480
Cutaneous oxygen monitor.	868.2500
Pneumotachometer.	868.2550
Airway pressure monitor.	868.2600

Product Classification Name	FDA Classification Regulation Number
(Identify the generic product type under which the product being reported on Compliant Products – FORM FDA 3474 is classified.)	(Enter the associated CFR number on Line #5 of Compliant Products – FORM FDA 3474.)
Gas pressure gauge.	868.2610
Gas pressure calibrator.	868.2620
Pressure regulator.	868.2700
Electrical peripheral nerve stimulator.	868.2775
Differential pressure transducer.	868.2875
Gas flow transducer.	868.2885
Gas pressure transducer.	868.2900
Emergency airway needle	868.5090
Nasopharyngeal airway.	868.5100
Oropharyngeal airway.	868.5110
Anesthesia conduction catheter.	868.5120
Anesthesia conduction filter.	868.5130
Anesthesia conduction kit.	868.5140
Anesthesia conduction needle.	868.5150
Gas machine for anesthesia or analgesia.	868.5160
Laryngotracheal topical anesthesia applicator.	868.5170
Rocking bed.	868.5180
Blow bottle.	868.5220
Anesthesia breathing circuit.	868.5240
Breathing circuit circulator.	868.5250
Breathing circuit bacterial filter.	868.5260
Breathing system heater.	868.5270
Breathing tube support.	868.5280
Carbon dioxide absorbent	868.5300
Carbon dioxide absorber.	868.5310
Reservoir bag.	868.5320
Breathing gas mixer.	868.5330
Nasal oxygen cannula.	868.5340
Nasal oxygen catheter.	868.5350
Posture chair for cardiac or pulmonary treatment.	868.5365
Heat and moisture condenser (artificial nose).	868.5375
Electroanesthesia apparatus.	868.5400
Ether hook.	868.5420
Gas-scavenging apparatus.	868.5430
Portable oxygen generator.	868.5440
Respiratory gas humidifier.	868.5450
Therapeutic humidifier for home use.	868.5460
Hyperbaric chamber.	868.5470
Flexible laryngoscope.	868.5530
Rigid laryngoscope.	868.5540
Anesthetic gas mask.	868.5550
Gas mask head strap.	868.5560
Nonbreathing mask.	868.5570
Oxygen mask.	868.5580
Scavenging mask.	868.5590
Venturi mask.	868.5600
Membrane lung for long-term pulmonary support.	868.5610
Breathing mouthpiece.	868.5620
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Product Classification Name	FDA Classification Regulation Number
(Identify the generic product type under which the product being reported on	(Enter the associated CFR number on Line #5 of
<u>Compliant Products – FORM FDA 3474</u> is classified.) Nebulizer.	Compliant Products – FORM FDA 3474.) 868.5630
Medicinal nonventilatory nebulizer (atomizer).	868.5640
Esophageal obturator.	868.5650
Portable liquid oxygen unit.	868.5655
Powered percussor.	868.5665
Rebreathing device.	868.5675
Incentive spirometer.	868.5690
Nonpowered oxygen tent.	868.5700
Electrically powered oxygen tent.	868.5710
Bronchial tube	
Tracheal tube.	868.5720 868.5730
Tracheal/bronchial differential ventilation tube.	868.5740
Inflatable tracheal tube cuff.	868.5750
Cuff spreader.  Tracheal tube fixation device.	868.5760
	868.5770
Tube introduction forceps.	868.5780
Tracheal tube stylet.	868.5790
Tracheal tube cleaning brush.	868.5795
Tracheostomy tube and tube cuff.	868.5800
Airway connector.	868.5810
Dental protector.	868.5820
Autotransfusion aparatus.	868.5830
Pressure tubing and accessories.	868.5860
Nonebreathing valve.	868.5870
Anesthetic vaporizer.	868.5880
Continuous ventilator.	868.5895
Noncontinuous ventilator (IPPB).	868.5905
Manual emergency ventilator.	868.5915
Powered emergency ventilator.	868.5925
External negative pressure ventilator.	868.5935
Intermitent mandatory ventilation attachment.	868.5955
Positive end expiratory pressure breathing attachment.	868.5965
Ventilator tubing.	868.5975
Tee drain (water trap).	868.5995
Anesthetic cabinet, table, or tray.	868.6100
Cardiopulmonary emergency cart.	868.6175
Nose clip.	868.6225
Portable air compressor.	868.6250
Calibration gas.	868.6400
Anesthesia stool.	868.6700
Tracheobronchial suction catheter	868.6810
Patient position support.	868.6820
Medical gas yoke assembly.	868.6885

Product Classification Name	FDA Classification Regulation Number
(Identify the generic product type under which the product being reported on Compliant Products – FORM FDA 3474 is classified.)	(Enter the associated CFR number on Line #5 of Compliant Products – FORM FDA 3474.)
CARDIOVASCULAR DEVICE	
Arrhythmia detector and alarm.	870.1025
Blood pressure alarm.	870.1100
Blood pressure computer.	870.1110
Blood pressure cuff.	870.1120
Noninvasive blood pressure measurement system.	870.1130
Venous blood pressure manometer.	870.1140
Diagnostic intravascular catheter.	870.1200
Continuous flush catheter.	870.1210
Electrode recording catheter or electrode recording probe.	870.1220
Fiberoptic oximeter catheter.	870.1230
Flow-directed catheter.	870.1240
Percutaneous catheter.	870.1250
Intracavitary phonocatheter system.	870.1270
Steerable catheter.	870.1280
Steerable catheter control system.	870.1290
Catheter cannula.	870.1300
Vessel dilator for percutaneous catheterization.	870.1310
Catheter guide wire.	870.1330
Catheter introducer.	870.1340
Catheter hittodicer:  Catheter balloon repair kit	870.1350
Trace microsphere.	870.1360
Catheter tip occuluder.	870.1370
Catheter stylet.	870.1380
Trocar.	870.1380
Programmable diagnostic computer.	870.1425
Single-function, preprogrammed diagnostic computer	870.1425
Densitometer.	870.1450
	870.1650
Angiographic injector and syringe.  Indicator injector.	870.1660
	870.1660
Syringe actuator for an injector.  External progammable pacemaker pulse generator.	870.1750
1 0 1	
Withdrawl-infusion pump.	870.1800
Stethoscope.	870.1875
Thermodilution probe.	870.1915
Biopotential amplifier and signal conditioner.	870.2050
Transducer signal amplifier and signal conditioner.	870.2060
Cardiovascular blood flowmeter.	870.2100
Extravascular blood flow probe.	870.2120
Cardiac monitor (including cardiotachometer and rate alarm).	870.2300
Apex cardiograph (vibrocardiograph).	870.2310
Ballistocardiograph.	870.2320
Echcocardiograph.	870.2330
Electrocardardiograph.	870.2340
Electrocardiograph lead switching adaptor.	870.2350
Electrocardiograph electrode.	870.2360
Electrocardiograph surface electrode tester.	870.2370

Product Classification Name	FDA Classification Regulation Number
(Identify the generic product type under which the product being reported on Compliant Products – FORM FDA 3474 is classified.)	(Enter the associated CFR number on Line #5 of Compliant Products – FORM FDA 3474.)
Phonocardiograph.	870.2390
Vectorcardiograph	870.2400
Medical cathode-ray tube display.	870.2450
Signal isolation system.	870.2600
Line isolation monitor.	870.2620
Portable leakage current alarm.	870.2640
Oscillometer.	870.2675
Oximeter.	870.2700
Ear oximeter.	870.2710
Impedance phlebograph.	870.2750
Impedance plethysmograph.	870.2770
Hydraulic, pneumatic, or photoelectric plethysmographs.	870.2780
Medical magnetic tape recorder.	870.2800
Paper chart recorder.	870.2810
Apex cardiographic transducer.	870.2840
Extravascular blood pressure transducer.	870.2850
Heart sound transducer.	870.2860
Catheter tip pressure transducer.	870.2870
Ultrasonic transducer.	870.2880
Vessel occlusion transducer.	870.2890
Patient transducer and electrode cable (including connector).	870.2900
Radiofrequency physiological signal transmitter and receiver.	870.2910
Telephone electrocardiograph transmitter and receiver.	870.2920
Vascular clip.	870.3250
Vena cava clip.	870.3260
Arterial embolization device.	870.3300
Cardiovascular intravascular filter.	870.3375
Vascular graft prosthesis of less than 6 millimeters diameter.	870.3450
Vascular graft prosthesis of 6 millimeters and greater	870.3460
Intracardiac patch or pledget made of polypropylene,	870.3470
Intra-aortic balloon and control system.	870.3535
Ventricular bypass (assist) device.	870.3545
External pacemaker pulse generator.	870.3600
Implantable pacemaker pulse generator.	870.3610
Pacemaker lead adaptor.	870.3620
Pacemaker generatory function analyzer.	870.3630
Indirect pacemaker generator function analyzer.	870.3640
Pacemaker polymeric mesh bag.	870.3650
Pacemaker charger.	870.3670
Cardiovascular permanent or temporary pacemaker	870.3680
Pacemaker magnet.	870.3690
Pacemaker programmers.	870.3700
Pacemaker repair or replacement material.	870.3710
Pacemaker electrode functiontester.	870.3720
Pacemaker service tools.	870.3730
Annuloplasty ring.	870.3800
Carotid sinus nerve stimulator.	870.3850
Replacement heart valve.	870.3925
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Product Classification Name	FDA Classification Regulation Number
(Identify the generic product type under which the product being reported on <u>Compliant Products – FORM FDA 3474</u> is classified.)	(Enter the associated CFR number on Line #5 of Compliant Products – FORM FDA 3474.)
Prosthetic heart valve holder.	870.3935
Prosthetic heart valve sizer.	870.3945
Endomyocardial biopsy device.	870.4075
Cardiopulmonary bypass accessory equipment.	870.4200
Cardiopulmonary bypass bubble detector.	870.4205
Cardiopulmonary bypass vascular catheter, cannula, or	870.4210
Cardiopulmonary bypass heart-lung machine console	870.4220
Cardiopulmonary bypass defoamer.	870.4230
Cardiopulmonary bypass heat exchanger.	870.4240
Cardiopulmonary bypass temperature controller.	870.4250
Cardiopulmonary bypass arterial line blood filter.	870.4260
Cardiopulmonary bypass cardiotomy suction line blood filter	870.4270
Cardiopulmonary prebypass filter.	870.4280
Cardiopulmonary bypass adaptor, stopcock, manifold, or	870.4290
Cardiopulmonary bypass gas control unit.	870.4300
Cardiopulmonary bypass coronary pressure gauge.	870.4310
Cardiopulmonary bypass pulsatile flow generator.	870.4320
Cardiopulmonary bypass on-line blood gas monitor.	870.4330
Cardiopulmonary bypass level sensing monitor and/or control.	870.4340
Cardiopulmonary bypass oxygenator.	870.4350
Nonroller-type cardiopulmonary bypass blood pump.	870.4360
Roller-type cardiopulmonary bypass blood pump.	870.4370
Cardiopulmonary bypass pump speed control.	870.4380
Cardiopulmonary bypass pump tubing.	870.4390
Cardiopulmonary bypass blood reservoir.	870.4400
Cardiopulmonary bypass in-line blood gas sensor.	870.4410
Cardiopulmonary bypass cardiotomy return sucker.	870.4420
Cardiopulmonary bypass intracardiac suction control.	870.4430
Vascular clamp.	870.4450
Surgical vessel dilator.	870.4475
Cardiovascular surgical instruments.	870.4500
Intraluminal artery stripper.	870.4875
External vein stripper.	870.4885
Patient care suction apparatus.	870.5050
Embolectomy catheter.	870.5150
Septostomy catheter.	870.5175
External cardiac compressor	870.5200
External counter-pulsating device.	870.5225
DC-defribrillator (including paddles).	870.5300
Defribrillator tester.	870.5325
External transcutaneous cardiac pacemaker (noninvasive).	870.5550
Compressible limb sleeve.	870.5800
Thermal regulating system.	870.5900
Automatic rotating tourniquet.	870.5925

Product Classification Name	FDA Classification Regulation Number
(Identify the generic product type under which the product being reported on Compliant Products – FORM FDA 3474 is classified.)	(Enter the associated CFR number on Line #5 of Compliant Products – FORM FDA 3474.)
DENTAL DEVICES – P	
Gingival fluid measurer.	872.1500
Pulp tester.	872.1720
Electrode gel for pulp tester.	872.1730
Caries detection device.	872.1740
Extraoral source x-ray system.	872.1800
Intraoral source x-ray system.	872.1810
Dental x-ray exposure alignment device.	872.1820
Cephalometer.	872.1830
•	872.1840
Dental x-ray position indicating device.  Lead-lined position indicator.	872.1850
•	
Dental x-ray film holder.	872.1905
Amalgam alloy.	872.3050
Gold based alloys and precious metal alloys for clinical use.	872.3060
Mercury and alloy dispenser.	872.3080
Dental amalgamator.	872.3100
Dental amalgam capsule.	872.3110
Preformed anchor.	872.3130
Resin applicator.	872.3140
Articulator.	872.3150
Precision attachment.	872.3165
Resin tooth bonding agent.	872.3200
Dental bur.	872.3240
Calcium hydroxide cavity liner.	872.3250
Cavity varnish.	872.3260
Dental cement.	872.3275
Preformed clasp.	872.3285
Hydrophilic resin coating for dentures.	872.3300
Coating material for resin fillings.	872.3310
Preformed crown.	872.3330
Gold or stainless steel cusp.	872.3350
Preformed cusp.	872.3360
Karaya and sodium borate with or without acacia denture	872.3400
Ethylene oxide homopolymer and/or carboxymethyl-cellulose	872.3410
Carboxymethylcellulose sodium and cationic polyacrylamide	872.3420
Ethylene oxide homopolymer and/or karaya denture	872.3450
Polyacrylamide polymer (modified cationic) denture adhesive.	872.3480
Carboxymethylcellulose sodium and/or polyvinylmethylether	872.3490
Polyvinylmethylether maleic anhydride (PVM-MA), acid	872.3500
OTC denture cleanser.	872.3520
Mechanical denture cleaner	872.3530
OTC denture cushion or pad.	872.3540
OTC denture reliner.	872.3560
OTC denture repair kit.	872.3570
Preformed gold denture tooth.	872.3580
Preformed plastic denture tooth.	872.3590
Partially fabricated denture kit.	872.3600
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Product Classification Name (Identify the generic product type under which the product being reported on Compliant Products – FORM FDA 3474 is classified.)	FDA Classification Regulation Number (Enter the associated CFR number on Line #5 of Compliant Products – FORM FDA 3474.)
Endosseous implant.	872.3640
Subperiosteal implant material.	872.3645
Impression material.	872.3660
Resin impression tray material.	872.3670
Polytetrafluoroethylene (PTFE) vitreous carbon material.	872.3680
Dental mercury.	872.3700
Base metal alloy.	872.3710
Pantograph.	872.3730
Retentive and splinting pin.	872.3740
Bracket adhesive resin and tooth conditioner.	872.3750
Denture relining, repairing, or rebasing resin.	872.3760
Pit and fissure sealant and conditioner.	872.3765
Temporary crown and bridge resin.	872.3770
Root canal post.	872.3810
Root canal filling resin.	872.3820
Endodontic paper point	872.3830
Endodontic silver point.	872.3840
Gutta percha.	872.3850
Endodontic stabilizing splint.	872.3890
Posterior artificial tooth with a metal insert.	872.3900
Backing and facing for an artificial tooth.	872.3910
Porcelain tooth.	872.3920
Tricalcium phosphate granules for dental bone repair.	872.3930
Total temporomandibular joint prosthesis.	872.3940
Glenoid fossa prosthesis.	872.3950
Mandibular condyle prosthesis.	872.3960
Interarticular disc prosthesis (interpositional implant).	872.3970
Bone cutting instrument and accessories.	872.4120
Intraoral dental drill.	872.4130
Dental handpiece and accessories.	872.4200
Gas-powered jet injector.	872.4465
Spring-powered jet injector.	872.4475
Dental diamond instrument.	872.4535
Dental hand instrument.	872.4565
Intraoral ligature and wire lock.	872.4600
Fiber optic dental light.	872.4620
Dental operating light	872.4630
Dental injecting needle.	872.4730
Bone plate.	872.4760
Rotary scaler.	872.4840
Ultrasonic scaler.	872.4850
Intraosseous fixation screw or wire.	872.4880
Dental electrosurgical unit and accessories.	872.4920
Orthodontic appliance and accessories.	872.5410
Orthodontic plastic bracket.	872.5470
Extraoral orthodontic headgear.	872.5500
Preformed tooth positioner.	872.5525
Teething ring.	872.5550
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Product Classification Name (Identify the generic product type under which the product being reported on Compliant Products – FORM FDA 3474 is classified.)	FDA Classification Regulation Number (Enter the associated CFR number on Line #5 of Compliant Products – FORM FDA 3474.)
Abrasive device and accessories.	872.6010
Oral cavity abrasive polishing agent.	872.6030
Saliva absorber.	872.6050
Ultraviolet activator for polymerization.	872.6070
Airbrush.	872.6080
Anesthetic warmer.	872.6100
Articulation paper.	872.6140
Base plate shellac.	872.6200
Dental chair and accessories	872.6250
Prophylaxis cup.	872.6290
Rubber dam and accessories.	872.6300
Ultraviolet detector	872.6350
Dental floss.	872.6390
Heat source for bleaching teeth.	872.6475
Oral irrigation unit.	872.6510
Impression tube.	872.6570
Dental operative unit and accessories.	872.6640
Massaging pick or tip for oral hygiene.	872.6650
Porcelain powder for clinical use.	872.6660
Silicate protector.	872.6670
Boiling water sterilizer.	872.6710
Endodontic dry heat sterilizer.	872.6730
Cartridge syringe.	872.6770
Manual toothbrush.	872.6855
Powered toothbrush.	872.6865
Disposable fluoride tray.	872.6870
Preformed impression tray.	872.6880
Intraoral dental wax.	872.6890

Product Classification Name	FDA Classification Regulation Number
(Identify the generic product type under which the product being reported on <u>Compliant Products – FORM FDA 3474</u> is classified.)	(Enter the associated CFR number on Line #5 of Compliant Products – FORM FDA 3474.)
EAR, NOSE, AND THROAT DEV	
Audiometer.	874.1050
Acoustic chamber for audiometric testing.	874.1060
Short increment sensitivity index (SISI) adapter.	874.1070
Audiometer calibration set.	874.1080
Auditory impedance tester.	874.1090
Earphone cushion for audiometric testing.	874.1100
Electronic noise generator for audiometric testing.	874.1120
Electroglottograph.	874.1325
Gustometer.	874.1500
Air or water caloric stimulator.	874.1800
Surgical nerve stimulator/locator.	874.1820
Toynbee diagnostic tube.	874.1925
Hearing aid.	874.3300
Hearing aid calibrator and analysis system.	874.3310
Group hearing aid or group auditory trainer.	874.3320
Master hearing aid.	874.3330
Battery-powered artificial larynx.	874.3375
Tinnitius masker.	874.3400
Middle ear mold.	874.3430
Partial ossicular replacement prosthesis.	874.3450
Total ossicular replacement prosthesis.	874.3495
Prosthesis modification instrument for ossicular replacement	874.3540
Ear, nose, and throat synthetic polymer material.	874.3620
Mandibular implant facial prosthesis.	874.3695
Laryngeal prosthesis (Taub design).	874.3730
Sacculotony tack (Cody tack).	874.3760
Endolymphatic shunt.	874.3820
Endolymphatic shunt tube with valve.	874.3850
Tympanostomy tube.	874.3880
Tympanostomy tube with semipermeable membrane.	874.3930
Epistaxis balloon.	874.4100
Ear, nose, and throat bur.	874.4140
Nasopharyngeal catheter.	874.4175
Ear, nose, and throat electric or pneumatic surgical drill.	874.4250
Ear, nose, and throat fiberoptic light source and carrier.	874.4350
Ear, nose, and throat manual surgical instrument.	874.4420
Argon laser for otology, rhinology, and laryngology.	874.4490
Ear, nose, and throat microsurgical carbon dioxide laser.	874.4500
Bronchoscope (flexible or rigid) and accessories.	874.4680
Esophagoscope (flexible or rigid) and accessories.	874.4710
Mediastinoscope and accessories.	874.4720
Laryngostroboscope.	874.4750
Nasopharyngoscope (flexible or rigid) and accessories.	874.4760
Otoscope.	874.4770
Ear, nose, and throat drug administration device.	874.5220
Ear, nose, and throat examination and treatment unit.	874.5300

Product Classification Name (Identify the generic product type under which the product being reported on Compliant Products – FORM FDA 3474 is classified.)	FDA Classification Regulation Number (Enter the associated CFR number on Line #5 of Compliant Products – FORM FDA 3474.)
Suction antichoke device.	874.5350
Tongs antichoke device	874.5370
Powered nasal irrigator.	874.5550
External nasal splint.	874.5800
Antistammering device.	874.5840

Product Classification Name (Identify the generic product type under which the product being reported on Compliant Products – FORM FDA 3474 is classified.)	FDA Classification Regulation Number (Enter the associated CFR number on Line #5 of Compliant Products – FORM FDA 3474.)
GASTROENTEROLOGY-UROLOGY	DEVICES – PART 876
Gastroenterology-urology biopsy instrument.	876.1075
Stomach pH electrode.	876.1400
Endoscope and accessories.	876.1500
Urodynamics measurement system.	876.1620
Gastrointestinal motility monitoring system.	876.1725
Urine flow or volume measuring system.	876.1800
Enuresis alarm.	876.2040
Penile inflatable implant.	876.3350
Penile rigidity implant.	876.3630
Testicular prosthesis.	876.3750
Fiberoptic light ureteral catheter.	876.4020
Colostomy rod.	876.4270
Endoscopic electrosurgical unit and accessories.	876.4300
Gastroenterology-urology evacuator.	876.4370
Hemorrhoidal ligator.	876.4400
Electohydraulic lithotriptor.	876.4480
Mechanical lithotriptor.	876.4500
Gastroenterolgy-urology fiberoptic retractor.	876.4530
Ribdam.	876.4560
Interlocking urethral sound.	876.4590
Ureteral stent.	876.4620
Water jet renal stone dislodger system.	876.4650
Ureteral stone dislodger.	876.4680
Manual gastroenterolgoy-urology surgical instrument and	876.4730
Urethrotome.	876.4770
Urological table and accessories.	876.4890
Biliary catheter and accessories.	876.5010
Continent ileostomy catheter.	876.5030
Suprapubic urological catheter and accessories.	876.5090
Urological catheter and accessories.	876.5130
Urological clamp for males.	876.5160
Enema kit.	876.5210
Colonic irrigation system.	876.5220
Urine collector and accessories.	876.5250
Implanted electrical urinary continence device.	876.5270
Implanted mechanical/hydraulic urinary continence device.	876.5280
Nonimplanted electrical continence device.	876.5320
Esophageal dilator.	876.5365
Rectal dilator.	876.5450
Ureteral dilator.	876.5470
Urethral dilator.	876.5520
Blood access device and accessories.	876.5540
Sorbent regenerated dialysate delivery system for	876.5600
Peritoneal dialysis system and accessories.	876.5630
Water purification system for hemodialysis.	876.5665
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Product Classification Name (Identify the generic product type under which the product being reported on Compliant Products – FORM FDA 3474 is classified.)	FDA Classification Regulation Number (Enter the associated CFR number on Line #5 of Compliant Products – FORM FDA 3474.)
Hemodialyzer with disposable insert (Kiil type).	876.5830
High permeability hemodialysis system.	876.5860
Sorbent hemoperfusion system.	876.5870
Isolated kidney perfusion and transport system and	876.5880
Ostomy irrigator.	876.5895
Ostomy pouch and accessories.	876.5900
Protective garment for incontinence.	876.5920
Peritoneo-venous shunt.	876.5955
Hernia support.	876.5970
Gastrointestinal tube and accessories	876.5980

GNERAL AND PLASTIC SURGERY DEVICES – PART 878 Speculum and accessories. External facial fracture fixation appliance.  878.3250 Surgical mesh. 878.3300 Polytetrafluoroethylene with carbon fibers composite implant 878.3300 Silicone gel-filled breast prosthesis. 878.3530 Silicone gel-filled breast prosthesis. 878.3530 Silicone gel-filled breast prosthesis. 878.3540 Chin prosthesis. 878.3550 Ear prosthesis. 878.3590 Ear prosthesis. 878.3590 Esophageal prosthesis. 878.3590 Sophageal prosthesis. 878.3590 Esophageal prosthesis. 878.3610 Nose prosthesis. 878.3610 Nose prosthesis. 878.3720 External prosthesis adhesive. 878.3720 External prosthesis adhesive. 878.3750 External prosthesis adhesive. 878.3750 External prosthesis adhesive. 878.3910 Inflatable extremity splint. 878.3900 Noninflatable extremity splint. 878.3910 Plastic surgery kit and accessories. 878.3925 Surgical apparel. 878.4040 Organ bag. 878.4160 Introduction/drainage catheter and accessories. 878.4200 Implantable clip. 878.4300 Removable skin clip. 878.4320 Cryosurgical unit and accessories. 878.4370 Drape adhesive. 878.4370 Drape adhesive. 878.4370 Drape adhesive. 878.4440 Nonabsorbable gauze for internal use. 878.4440 Nonabsorbable powder for lubricating a surgeon's glove. 878.4450 Surgeon's gloving cream. 878.4460 Ultraviolet lamp for dermatologic disorders. 878.4660 Nonpowered, single patient, portable suction apparatus. 878.4750 Removable skin degreaser or adhesive tape solvent. 878.4750 Removable staple. 878.4750 Removable staple. 878.4760 Removable staple. 878.4750 Removable staple. 878.4760 Removable staple. 878.4750 Removable staple. 878.4760 Removable staple. 878.4750	Product Classification Name (Identify the generic product type under which the product being reported on Compliant Products – FORM FDA 3474 is classified.)	FDA Classification Regulation Number (Enter the associated CFR number on Line #5 of Compliant Products – FORM FDA 3474.)
External facial fracture fixation appliance.  Surgical mesh.  Polytetraffuoroethylene with carbon fibers composite implant  878.3300  Silicone inflatable breast prosthesis.  Silicone gel-filled breast gel-gel-gel-gel-gel-gel-gel-gel-gel-gel-	GENERAL AND PLASTIC SURGERY	DEVICES – PART 878
Surgical mesh. Polytetrafluoroethylene with carbon fibers composite implant 878.3500 Silicone inflatable breast prosthesis. Silicone gel-filled breast gel-gel-gel-gel-gel-gel-gel-gel-gel-gel-	Speculum and accessories.	878.1800
Surgical mesh. Polytetrafluoroethylene with carbon fibers composite implant 878.3500 Silicone inflatable breast prosthesis. Silicone gel-filled breast gel-gel-gel-gel-gel-gel-gel-gel-gel-gel-	•	878.3250
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Product Classification Name (Identify the generic product type under which the product being reported on Compliant Products – FORM FDA 3474 is classified.)	FDA Classification Regulation Number (Enter the associated CFR number on Line #5 of Compliant Products – FORM FDA 3474.)
Surgical instrument motors and accessories/attachments.	878.4820
Absorbable surgical gut suture.	878.4830
Suture retention device.	878.4930
Manual operating table and accessories and manual	878.4950
Operating tables and accessories and operating chairs and	878.4960
Nonabsorbable poly(ethylene terephthalate) surgical suture.	878.5000
Nonabsorbable polypropylene surgical suture.	878.5010
Nonabsorbable polyamide surgical suture.	878.5020
Natural nonabsorbable silk surgical suture.	878.5030
Air-handling apparatus for a surgical operating room.	878.5070
Needle-type epilator.	878.5350
Tweezer-type epilator.	878.5360
Topical oxygen chamber for extremities.	878.5650
Nonpneumatic tourniquet.	878.5900
Pneumatic tourniquet.	878.5910

Product Classification Name (Identify the generic product type under which the product being reported on Compliant Products – FORM FDA 3474 is classified.)	FDA Classification Regulation Number (Enter the associated CFR number on Line #5 of Compliant Products – FORM FDA 3474.)
GENERAL HOSPITAL AND PERSONAL	USE DEVICES – PART 880
Liquid crystal forehead temperature strip.	880.2200
Bed-patient monitor.	880.2400
Electronic monitor for gravity flow infusion systems.	880.2420
Electrically powered spinal fluid pressure monitor.	880.2460
Spinal fluid manometer.	880.2500
Stand-on patient scale.	880.2700
Patient scale.	880.2720
Surgical sponge scale.	880.2740
Sterilization process indicator.	880.2800
Clinical color change thermometer.	880.2900
Clinical electronic thermometer.	880.2910
Clinical mercury thermometer.	880.2920
I.V. container.	880.5025
Medical recirculating air cleaner.	880.5045
Elastic bandage.	880.5075
Liquid bandage.	880.5090
AC-powered adjustable hospital bed.	880.5100
Hydraulic adjustable hospital bed.	880.5110
Manual adjustable hospital bed.	880.5120
Infant radiant warmer.	880.5130
Pediatric hospital bed.	880.5140
Nonpowered flotation therapy matress.	880.5150
Therapeutic medical binder.	880.5160
Burn sheet.	880.5180
Intravascular catheter securement device.	880.5200
Medical adhesive tape and adhesive bandage.	880.5240
Neonatal eye pad.	880.5270
Medical absorbent fiber.	880.5300
Neonatal incubator.	880.5400
Neonatal transport incubator	880.5410
Pressure infusor for an I.V. bag.	880.5420
Nonelectrically powered fluid injector.	880.5430
Intravascular administration set.	880.5440
Patient care reverse isolation chamber.	880.5450
Jet lavage.	880.5475
AC-powered patient lift.	880.5500
Non-AC-powered patient lift.	880.5510
Alternating pressure air flotation mattress.	880.5550
Temperature regulated water matress.	880.5560
Hypodermic single lumen needle.	880.5570
Acupuncture needle.	880.5580
Nipple shield.	880.5630
Lamb feeding nipple.	880.5640
Pediatric position holder.	880.5680
Neonatal phototherapy unit.	880.5700
Infusion pump.	880.5725
masion painty.	555.5725

Product Classification Name (Identify the generic product type under which the product being reported on Compliant Products – FORM FDA 3474 is classified.)	FDA Classification Regulation Number (Enter the associated CFR number on Line #5 of Compliant Products – FORM FDA 3474.)
Suction snakebite kit.	880.5740
Chemical cold pack snakebite kit.	880.5760
Medical support stocking.	880.5780
Therapeutic scrotal support.	880.5820
Piston syringe.	880.5860
Umbilical occlusion device.	880.5950
Absorbent tipped applicator.	880.6025
Ice bag.	880.6050
Medical disposable bedding.	880.6060
Bed board.	880.6070
Cardiopulmonary resuscitation board.	880.6080
Hot/cold water bottle.	880.6085
Ethylene oxide gas aerator cabinet.	880.6100
Medical chair and table.	880.6140
Ultrasonic cleaner for medical instruments.	880.6150
[Reserved]	880.6175
Cast cover.	880.6185
Mattress cover for medical purposes.	880.6190
Ring cutter	880.6200
Tongue depressor.	880.6230
Patient examination glove.	880.6250
Examination gown.	880.6265
Medical insole.	880.6280
AC-powered medical examination light.	880.6320
Battery-powered medical examination light.	880.6350
Patient lubricant.	880.6375
Liquid medication dispenser.	880.6430
Skin pressure protectors.	880.6450
Medical ultraviolet air purifier.	880.6500
Medical ultraviolet water purifier.	880.6710
Body waste receptacle.	880.6730
Vacuum-powered body fluid suction apparatus.	880.6740
Protective restraint.	880.6760
Powered patient transfer device.	880.6775
Manual patient transfer device.	880.6785
Washer for body waste receptacles.	880.6800
Sterilization wrap.	880.6850
Ethylene oxide gas sterilizer.	880.6860
Dry-heat sterilizer.	880.6870
Steam sterilizer.	880.6880
Hand-carried stretcher.	880.6900
Wheeled stretcher.	880.6910
Syringe needle introducer.	880.6920
Irrigating syringe.	880.6960
Liquid crystal vein locator.	880.6970
Vein stabilizer.	880.6980

Product Classification Name	FDA Classification Regulation Number
(Identify the generic product type under which the product being reported or Compliant Products – FORM FDA 3474 is classified.)	(Enter the associated CFR number on Line #5 of Compliant Products – FORM FDA 3474.)
NEUROLOGICAL DEVICE	
Rigidit analyzer.	882.1020
Ataxiagraph.	882.1030
Two-point discriminator.	882.1200
Echoencephalograph.	882.1240
Electroconductive media.	882.1275
Cortical electrode.	882.1310
Cutaneous electrode.	882.1320
Depth electrode.	882.1330
Nasopharyngeal electrode.	882.1340
Needle electrode.	882.1350
Electroencephalograph.	882.1400
Electroenceophalograph electrode/lead tester.	882.1410
Electroencephalogram (EEG) signal spectrum analyzer.	882.1420
Electroencephalograph test signal generator.	882.1430
Nystagmograph.	882.1460
Neurological endoscope.	882.1480
Esthesiometer.	882.1500
Tuning fork.	882.1525
Galvanic skin response measurement device.	882.1540
Nerve conduction velocity measurement device.	882.1550
Skin potential measurement device.	882.1560
Powered direct-contact temperature measurement device.	882.1570
Alpha monitor.	882.1610
Intracranial pressure monitoring device.	882.1620
Percussor.	882.1700
Pinwheel.	882.1750
Ocular plethysmograph.	882.1790
	882.1825
Rheoencephalograph Physiological signal amplifier.	882.1835
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Physiological signal conditioner.	882.1845
Electroencephalogram (EEG) telemetry system.	882.1855
Evoked response electrical stimulator.	882.1870
Evoked response mechanical stimulator.	882.1880
Evoked response photic stimulator.	882.1890
Evoked response auditory stimulator.	882.1900
Ultrasonic scanner calibration test block.	882.1925
Tremor transducer.	882.1950
Skull plate anvil.	882.4030
Ventricular cannula.	882.4060
Ventricular catheter.	882.4100
Neurosurgical chair.	882.4125
Scalp clip.	882.4150
Aneurysm clip applier.	882.4175
Clip forming/cutting instrument.	882.4190
Clip removal instrument.	882.4200
Clip rack.	882.4215

Product Classification Name	FDA Classification Regulation Number
(Identify the generic product type under which the product being reported on <b>Compliant Products – FORM FDA 3474</b> is classified.)	(Enter the associated CFR number on Line #5 of Compliant Products – FORM FDA 3474.)
Cryogenic surgical device.	882.4250
Dowel cutting instrument.	882.4275
Manual cranial drills, burrs, trephines, and their accessories.	882.4300
Powered compound cranial drills, burrs, trephines, and their	882.4305
Powered simple cranial drills, burrs, trephines, and their	882.4310
Cranial drill handpiece (brace).	882.4325
Electric cranial drill motor.	882.4360
Pneumatic cranial drill motor.	882.4370
Radiofrequency lesion generator.	882.4400
Neurosorgical headrests.	882.4440
Neurosurgical head holder (skull clamp).	882.4460
Cranioplasty material forming instrument.	882.4500
Microsurgical instrument.	882.4525
Nonpowered neurosurgical instrument.	882.4535
Shunt system implantation instrument.	882.4545
Stereotaxic instrument.	882.4560
Leukotome.	882.4600
Neurosurgical suture needle.	882.4650
Cottonoid paddle.	882.4700
Radiofrequency lesion probe.	882.4725
Skull punch.	882.4750
Self-retaining retractor for neurosurgery.	882.4800
Manual rongeur.	882.4840
Powered rongeur.	882.4845
Skullplate screwdriver.	882.4900
Methylmethacrylate for aneurysmorrhaphy.	882.5030
Biofeedback device.	882.5050
Bite block.	882.5070
Intravascular occluding catheter.	882.5150
Cartoid artery clamp.	882.5175
Aneurysm clip.	882.5200
Implanted malleable clip.	882.5225
Aversive conditioning device.	882.5235
Burr hole cover.	882.5250
Nerve cuff.	882.5275
Methyl methacrylate for cranioplasty	882.5300
Preformed alterable cranioplasty plate.	882.5320
Preformed nonalterable cranioplasty plate.	882.5330
Cranioplasty plate fastener.	882.5360
Lesion temperature monitor.	882.5500
Central nervous system fluid shunt and components.	882.5550
Cranial electrotheraphy stimulator.	882.5800
External functional neuromuscular stimulator.	882.5810
Implanted cerebellar stimulator.	882.5820
Implanted diaphragmatic/phrenic nerve stimulator.	882.5830
Implanted diaprilaginatic/priteric fierve stimulator.  Implanted intracerebral/subcortical stimulator for pain relief.	882.5840
Implanted intracerebra/subcortical stirridator for pain relier.	882.5850
Implanted spirial cord stimulator for bladder evacuation.	882.5860
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Product Classification Name (Identify the generic product type under which the product being reported on Compliant Products – FORM FDA 3474 is classified.)	FDA Classification Regulation Number (Enter the associated CFR number on Line #5 of Compliant Products – FORM FDA 3474.)
Implanted peripheral nerve stimulator for pain relief.	882.5870
Implanted spinal cord stimulator for pain relief.	882.5880
Transcutaneous electrical nerve stimulator for pain relief.	882.5890
Preformed craniosynostosis strip.	882.5900
Dura substitute.	882.5910
Electroconvulsive therapy device.	882.5940
Artificial embolization device.	882.5950
Skull tongs for traction.	882.5960

Product Classification Name (Identify the generic product type under which the product being reported on Compliant Products – FORM FDA 3474 is classified.)	FDA Classification Regulation Number (Enter the associated CFR number on Line #5 of Compliant Products – FORM FDA 3474.)
OBSTETRICAL AND GYNECOLOGICA	AL DEVICES – PART 884
Viscometer for cervical mucus.	884.1040
Endocervical aspirator.	884.1050
Endometrial aspirator.	884.1060
Endometrial brush.	884.1100
Endometrial suction curette and accessories.	884.1175
Endometrial washer.	884.1185
Uterotubal carbon dioxide insufflator and accessories.	884.1300
Perineometer.	884.1425
Amniotic fluid sampler (anmiocentesis tray).	884.1550
Fetal blood sampler.	884.1560
Transabdominal amnioscope (fetoscope) and accessories.	884.1600
Colposcope.	884.1630
Culdoscope and accessories.	884.1640
Transcervical endoscope (amnioscope) and accessories.	884.1660
Hysteroscope and accessories.	884.1690
Hysteroscopic insufflator.	884.1700
Gynecologic laparoscope and accessories.	884.1720
laparoscopic insufflator.	884.1730
Obstetric data analyzer.	884.2050
Obstetric-gynecologic ultrasonic imager.	884.2225
Fetal ultrasonic monitor and accessories.	884.2600
Fetal scalp circular (spiral) electrode and applicator.	884.2675
Fetal scalp clip electrode and applicator.	884.2685
Intrauterine pressure monitor and accessories.	884.2700
External uterine contraction monitor and accessories.	884.2720
Perinatal monitoring system and accessories.	884.2740
Fetal stethoscope.	884.2900
Obstetric ultrasonic transducer and accessories.	884.2960
Telethermographic system.	884.2980
Liquid crystal thermographic system.	884.2982
Cervical drain.	884.3200
Vaginal pessary.	884.3575
Fallopian tube prosthesis.	884.3650
Vaginal stent.	884.3900
Endoscopic electrocautery and accessories.	884.4100
Gynecologic electrocautery and accessories.	884.4120
Bipolar endoscopic coagulator-cutter and accessories.	884.4150
Unipolar endoscopic coagulator-cutter and accessories.	884.4160
Expandable cervical dilator.	884.4250
Hygroscopic Laminaria cervical dilator.	884.4260
Vibratory cervical dilators.	884.4270
Fetal vacuum extractor.	884.4340
Obstetric forceps.	884.4400
Obstetric fetal destructive instrument.	884.4500
Obstetric-gynecologic general manual instrument.	884.4520
Obstetric-gynecologic specialized manual instrument.	884.4530

Product Classification Name (Identify the generic product type under which the product being reported on Compliant Products – FORM FDA 3474 is classified.)	FDA Classification Regulation Number (Enter the associated CFR number on Line #5 of Compliant Products – FORM FDA 3474.)
Gynecologic surgical laser.	884.4550
Obstetric table and accessories	884.4900
Metreurynter-balloon abortion system.	884.5050
Vacuum abortion system.	884.5070
Obstetric anesthesia set	884.5100
Nonpowered breast pump.	884.5150
Powered breast pump.	884.5160
Abdominal decompression chamber.	884.5225
Cervical cap.	884.5250
Condom.	884.5300
Condom with spermicidal lubricant.	884.5310
Glans sheath.	884.5320
Contraceptive diaphragm and accessories.	884.5350
Contraceptive intrauterine device (IUD) and introducer.	884.5360
Contraceptive tubal occlusion device (TOD) and introducer.	884.5380
Perineal heater.	884.5390
Menstrual cup.	884.5400
Scented or scented deoderized menstrual pad.	884.5425
Unscented menstrual pad.	884.5435
Scented or scented deodorized menstrual tampon.	884.5460
Unscented menstrual tampon.	884.5470
Therapeutic vaginal douche apparatus.	884.5900
Vaginal insufflator.	884.5920
Powered vaginal muscle stimulator for therapeutic use.	884.5940
Genital vibrator for therapeutic use.	884.5960

(Enter the associated CFR number on Line #5 of Compliant Products – FORM FDA 3474.)
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<b>PART 886</b>
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Product Classification Name	FDA Classification Regulation Number
(Identify the generic product type under which the product being reported on Compliant Products – FORM FDA 3474 is classified.)	(Enter the associated CFR number on Line #5 of Compliant Products – FORM FDA 3474.)
Ophthalmic isotope uptake probe.	886.1670
Ophthalmic projector.	886.1680
Pupillograph.	886.1690
Pupillometer.	886.1700
Skiascopic rack.	886.1750
Ophthalmic refractometer.	886.1760
Manual refractor.	886.1770
Retinoscope.	886.1780
Nearpoint ruler.	886.1790
Schirmer strip.	886.1800
Tangent screen (campimeter).	886.1810
Simulatan (including crossed cylinder).	886.1840
AC-powered slitlamp biomicroscope.	886.1850
Ophthalmic instrument stand.	886.1860
Stereoscope.	886.1870
Fusion and stereoscopic target.	886.1880
Nystagmus tape.	886.1905
Spectacle dissociation test system.	886.1910
Tonometer sterilizer.	886.1940
Transilluminator.	886.1945
Ophthalmic tantalum clip.	886.3100
Ophthalmic conformer.	886.3130
Artificial eye.	886.3200
Absorbable implant (scleral buckling method).	886.3300
Eye sphere implant.	886.3320
Extraocular orbital implant.	886.3340
Keratoprosthesis.	886.3400
Intraocular lens.	886.3600
Scleral shell.	886.3800
	886.3920
Eye valve implant.  Powered corneal burr.	886.4070
Radiofrequency electrosurgical cautery apparatus.	886.4100
Thermal cautery unit.	886.4115
Vitreous aspiration and cutting instrument.	886.4150
Cryophthalmic unit.	886.4170
Ophthalmic knife test drum.	886.4230
Ophthalmic electrolysis unit.	886.4250
Intraocular gas.	886.4270
Intraocular pressure measuring device.	886.4280
Intraocular lens guide.	886.4300
Operating headlamp.	886.4335
Manual ophthalmic surgical instrument.	886.4350
Ocular surgery irrigation device.	886.4360
Keratome.	886.4370
Ophthalmic laser.	886.4390
Nd:YAG laser for posterior capsulotomy.	886.4392
Electronic metal locator.	886.4400
AC-powered magnet.	886.4440

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Permanent magnet.	886.4445
Ophthalmic surgical marker.	886.4570
Ocular pressure applicator.	886.4610
Phacofragmentation system.	886.4670
Ophthalmic photocoagulator.	886.4690
Ophthalmic eye shield.	886.4750
Ophthalmic operating spectacles (loupes).	886.4770
Ophthalmic sponge.	886.4790
Ophthalmic instrument table.	886.4855
Ophthalmic beta radiation source.	886.5100
Low-power binocular loupe.	886.5120
Contact lens inserter/remover.	886.5420
Low-vision magnifier.	886.5540
Ptosis crutch.	886.5600
Ophthalmic bar reader.	886.5800
Ophthalmic prism reader.	886.5810
Closed-circuit television reading system.	886.5820
Magnifying spectacles.	886.5840
Spectacle frame.	886.5842
Prescription spectacle lens.	886.5844
Prescription spectacle lens.	886.5850
Low-vision telescope.	886.5870
Electronic vision aid.	886.5900
Image intensification vision aid.	886.5910
Optical vision aid.	886.5915
Rigid gas permeable contact lens.	886.5916
Rigid gas permeable contact lens solution.	886.5918
Soft (hydrophilic) contact lens.	886.5925
Soft (hydrophilic) contact lens solution.	886.5928
[Reserved]	886.5933

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ORTHOPEDIC DEVICES -	
Arthroscope.	888.1100
AC-powered dynamometer.	888.1240
Nonpowered dynamometer.	888.1250
Goniometer.	888.1500
Nonpowered goniometer.	888.1520
Bone cap.	888.3000
Bone fixation cerclage.	888.3010
Bone heterograft.	888.3015
Intramedullary fixation rod.	888.3020
Passive tendon prosthesis.	888.3025
Polymethylmethacrylate (PMMA) bone cement.	888.3027
Single/multiple component metallic bone fixation appliances	888.3030
Smooth or threaded metallic bone fixation fastener.	888.3040
Spinal interlaminal fixation orthosis.	888.3050
Spinal intervertebral body fixation orthosis.	888.3060
Ankle joint metal/composite semiconstrained cemented	888.3100
Ankle joint metal/composite semi-constrained cemented	888.3110
Ankle joint metal/polymer non-constrained cemented	888.3120
Elbow joint metal/metal or metal/polymer constrained	888.3150
Elbow joint metal/polymer semi-constrained cemented	888.3160
Elbow joint radial (hemi-elbow) polymer prosthesis.	888.3170
Elbow joint humeral (hemi-elbow) metallic uncemented	888.3180
Finger joint metal/metal constrained uncemented prosthesis.	888.3200
Finger joint metal/metal constrained uncernented prostriesis.	888.3210
<u> </u>	888.3220
Finger joint metal/polymer constrained cemented prosthesis.  Finger joint polymer constrained prosthesis.	888.3230
Hip joint metal constrained cemented or uncemented	888.3300
. ,	888.3310
Hip joint metal/polymer constrained cemented or uncemented Hip joint metal/metal semi-constrained, with a cemented	888.3320
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Hip joint metal/metal semi-constrained, with an uncemented	888.3330
Hip joint metal/composite semi-constrained cemented	888.3340
Hip joint metal/polymer semi-constrained cemented	888.3350
Hip joint metal/ceramic/polymer semi-constrained cemented	888.3353
Hip joint metal/polymer/metal semi-constrained porous-coated	888.3358
Hip joint femoral (hemi-hip) acetabular metallic cemented or	888.3360
Hip joint (hemi-hip) acetabular metal cemented prosthesis.	888.3370
Hip joint femoral (hemi-hip) trunnion-bearing metal/polyacetal	888.3380
Hip joint femoral (hemi-hip) metal/polymer cemented or	888.3390
Hip joint femoral (hemi-hip) metallic resurfacing prosthesis.	888.3400
Hip joint metal/polymer semi-constrained resurfacing	888.3410
Knee joint femorotibial metallic constrained cemented	888.3480
Knee joint femorotibial metal/composite non-constrained	888.3490
Knee joint femorotibial metal/composite semi-constrained	888.3500
Knee joint femorotibial metal/composite semi-constrained	888.3510
Knee joint femorotibial metal/polymer non-constrained	888.3520
Knee joint femorotibial metal/polymer semi-constrained	888.3530

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Knee joint patellofemoral polymer/metal semi-constrained	888.3540
Knee joint patellofemorotibial polymer/metal/metal	888.3550
Knee joint patellofemorotibial polymer/metal/polymer semi-	888.3560
Knee joint femoral (hemi-knee) metallic uncemented	888.3570
Knee joint patellar (hemi-knee) metallic resurfacing	888.3580
Knee joint tibial (hemi-knee) metallic resurfacing uncemented	888.3590
Shoulder joint metal/metal or metal/polymer constrained	888.3640
Shoulder joint metal/polymer non-constrained cemented	888.3650
Shoulder joint metal/polymer semi-constrained cemented	888.3660
Shoulder joint glenoid (hemi-shoulder) metallic cemented	888.3680
Shoulder joint humeral (hemi-shoulder) metallic uncemented	888.3690
Toe joint polymer constrained prosthesis.	888.3720
Toe joint phalangeal (hemi-toe) polymer prosthesis.	888.3730
Wrist joint carpal lunate polymer prosthesis.	888.3750
Wrist joint carpal scaphoid polymer prosthesis.	888.3760
Wrist joint carpal trapexium polymer prosthesis.	888.3770
Wrist joint polymer constrained prosthesis.	888.3780
Wrist joint polymer constrained prosthesis.	888.3790
Wrist joint metal/polymer semi-constrained cemented	888.3800
Wrist joint ulnar (hemi-wrist) polymer prosthesis.	888.3810
Calipers for clinical use.	888.4150
Cement dispenser.	888.4200
Cement mixer for clinical use.	888.4210
Cement monomer vapor evacuator.	888.4220
Cement ventilation tube.	888.4230
Depth gauge for clinical use.	888.4300
Orthopedic manual surgical instrument.	888.4540
Sonic surgical instrument and accessories/attachments.	888.4580
Protractor for clinical use.	888.4600
Template for clinical use.	888.4800
Nonpowered orthopedic traction apparatus and accessories.	888.5850
Noninvasive traction component.	888.5890
Cast component.	888.5940
Cast removal instrument.	888.5960
Manual cast application and removal instrument.	888.5980

Product Classification Name	FDA Classification Regulation Number	
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PHYSICAL MEDICINE DEVICES – PART 890		
Electrode cable.	890.1175	
Chronaximeter	890.1225	
Diagnostic electromyograph.	890.1375	
Diagnostic electromyograph needle electrode.	890.1385	
Powered reflex hammer.	890.1450	
Force-measuring platform.	890.1575	
Intermittent pressure measurement system.	890.1600	
Miniature pressure transducer.	890.1615	
Diagnostic muscle stimulator.	890.1850	
Prosthetic and orthotic accessory.	890.3025	
Cane.	890.3075	
Mechanical chair.	890.3100	
Electric positioning chair.	890.3110	
Crutch.	890.3150	
Flotation cushion.	890.3175	
External limb orthotic component.	890.3410	
External limb prosthetic component.	890.3420	
Limb orthosis.	890.3475	
Truncal orthosis.	890.3490	
External assembled lower lib prosthesis.	890.3500	
Plinth.	890.3520	
Rigid pneumatic structure orthosis.	890.3610	
Arm sling.	890.3640	
Congenital hip dislocation abduction splint.	890.3665	
Denis Brown splint.	890.3675	
Powered wheeled stretcher.	890.3690	
Nonpowered communication system.	890.3700	
Powered communication system.	890.3710	
Powered environmental control system.	890.3725	
Mechanical table.	890.3750	
Powered table.	890.3760	
Cane, crutch, and walker tips and pads.	890.3790	
Motorized three-wheeled vehicle.	890.3800	
Mechanical walker.		
Mechanical wheelchair.	890.3825 890.3850	
Powered wheelchair.		
	890.3860	
Special grade wheelchair. Stair-climbing wheelchair.	890.3880	
	890.3890	
Standup wheelchair.	890.3900	
Wheelchair accessory.	890.3910	
Wheelchair component.	890.3920	
Wheelchair elevator.	890.3930	
Wheelchair platform scale.	890.3940	
Daily activity assist device.	890.5050	
Immersion hydrobath.	890.5100	
Paraffin bath.	890.5110	

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Nonpowered sitz bath.	890.5125
Powered patient transport.	890.5150
Air-fluidized bed.	890.5160
Powered flotation therapy bed	890.5170
Manual patient rotation bed.	890.5180
Powered patient rotation bed.	890.5225
Moist steam cabinet.	890.5250
Microwave diathermy.	890.5275
Shortwave diathermy.	890.5290
Ultrasonic diathermy.	890.5300
Exercise component.	890.5350
Measuring exercise equipment	890.5360
Nonmeasuring exercise equipment.	890.5370
Powered exercise equipment.	890.5380
Powered finger exerciser.	890.5410
Infrared lamp.	890.5500
Iontophoresis device.	890.5525
Powered external limb overload warning device.	890.5575
Powered inflatable tube massager.	890.5650
Therapeutic massager.	890.5660
Cold pack.	890.5700
Hot or cold disposable pack.	890.5710
Water circulating hot or cold pack.	890.5720
Moist heat pack	890.5730
Powered heating pad.	890.5740
Pressure-applying device.	890.5765
Powered muscle stimulator.	890.5850
Ultrasound and muscle stimulator.	890.5860
Multi-function physical therapy table.	890.5880
Powered traction equipment.	890.5900
Traction accessory.	890.5925
Chilling unit.	890.5940
Powered heating unit.	890.5950
Therapeutic vibrator.	890.5975

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RADIOLOGY DEVICES –	PART 892
Magnetic resonance diagnostic device.	892.1000
Scintillation (gamma) camera.	892.1100
Positron camera.	892.1110
Nuclear whole body counter.	892.1130
Bone densitometer.	892.1170
Emission computed tomography system.	892.1200
Fluorescent scanner.	892.1220
Nuclear rectilinear scanner	892.1300
Nuclear tomography system.	892.1310
Nuclear uptake probe.	892.1320
Nuclear whole body scanner	892.1330
Nuclear scanning bed.	892.1350
Radionuclide dose calibrator.	892.1360
Nuclear anthropomorphic phantom.	892.1370
Nuclear flood source phantom.	892.1380
Radionuclide rebreathing system.	892.1390
Nuclear sealed calibration source.	892.1400
Nuclear electrocardiograph synchronizer.	892.1410
Radionuclide test patter phantom.	892.1420
Nonfetal ultrasonic monitor.	892.1540
Ultrasonic pulsed doppier imaging system.	892.1550
Ultrasonic pulsed echo imaging system.	892.1560
Diagnostic ultrasonic transducer.	892.1570
Angiographic x-ray system.	892.1600
Diagnostic x-ray beam-limiting device.	892.1610
Cine or spot fluorographic x-ray camera.	892.1620
Electrostatic x-ray imaging system.	892.1630
Radiographic film marking system.	892.1640
Image-intensified fluoroscopic x-ray system.	892.1650
Non-image-intensified fluoroscopic x-ray system.	892.1660
Spot-film device.	892.1670
Stationary x-ray system.	892.1680
Diagnostic x-ray high voltage generator.	892.1700
Mammographic x-ray system.	892.1710
Mobile x-ray system.	892.1720
Photofluorographic x-ray system.	892.1730
Tomographic x-ray system.	892.1740
Computed tomography x-ray system.	892.1750
Diagnostic x-ray tube housing assembly.	892.1760
Diagnostic x-ray tube mount.	892.1770
Pneumoencephalographic chair.	892.1820
Radiologic patient cradle.	892.1830
Radiographic film.	892.1840
Radiographic film cassette.	892.1850
Radiographic film/cassette changer.	892.1860
Radiographic film/cassette changer programmer.	892.1870

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Wall-mounted radiographic cassette holder.	892.1880
Radiographic film illuminator.	892.1890
Automatic radiographic film processor.	892.1900
Radiographic grid.	892.1910
Radiographic head holder.	892.1920
Radiologic quality assurance instrument.	892.1940
Radiographic anthropomorphic phantom.	892.1950
Radiographic intensifying screen.	892.1960
Radiographic ECG/respirator synchronizer.	892.1970
Radiographic table.	892.1980
Transilluminator for breast evaluation.	892.1990
Medical charged-particle radiation therapy system.	892.5050
Medical neutron radiation therapy system.	892.5300
Manual radionuclide applicator system.	892.5650
Remote controlled radionuclide applicator system.	892.5700
Radiation therapy beam-shaping block.	892.5710
Radionuclide brachytherapy source.	892.5730
Radionuclide teletherapy source.	892.5740
Radionuclide radiation therapy system.	892.5750
Powered radiation therapy patient support assembly.	892.5770
Light beam patient position indicator.	892.5780
Radiation therapy stimulation system.	892.5840
X-ray radiation therapy system.	892.5900
Therapeutic x-ray tube housing assembly.	892.5930
Personnel protective shield.	892.6500