3 PRODUCT IDENTIFICATION

Classified medical gloves, accessories to gloves, and a few industrial gloves are briefly described in this chapter. The classification names and numbers for these medical devices are listed in Tables 3.1 and 3.2 because this information is needed when assembling a 510(k) submission. All references listed below are to Title 21 of the Code of Federal Regulations (CFR).

EXAMINATION GLOVES (PATIENT)

Under the proposed l999 rule, patient examination gloves would be classified as follows:

§880.6250 Patient examination gloves, powdered.

(a) Identification. A powdered patient examination glove is a disposable device made of natural rubber latex or synthetic material that bears powder to facilitate donning and is intended to be worn on the hand or finger(s) for medical purposes to provide a barrier against potentially infectious materials and other contaminants.

(b) Classification. Class II special controls are as follows:

(1) Guidance document. The Center for Devices and Radiological Health, FDA, "Medical Glove Guidance Manual," revised July_1999.

(2) Labeling. User labeling requirements in §801.440 of this chapter.

§880.6251 Patient examination gloves, powder-free.

(a) Identification. A powder-free patient examination glove is a disposable device made of natural rubber latex or synthetic material that may bear a trace amount of glove powder and is intended to be worn on the hand or finger(s) for medical purposes to provide a barrier against potentially infectious materials and other contaminants.

(b) Classification. Class II special controls are as follows:

(1) Guidance document. The Center for Devices and Radiological Health, FDA, ``Medical Glove Guidance Manual,'' as revised.

(2) Labeling. User labeling requirements in §801.440 of this chapter.

Examination gloves are proposed for reclassification into Class II, and if they become class II, new or modified examination gloves will be required to meet the design controls in §820.30 of the QS regulation.

Table 3.1 POWDERED Patient Examination Glove Proposed Classification

Common Name	Product Code	*21 CFR Classification Number	CLASS**
Vinyl (PVC)	80LYZ	880.6250	II
Latex	80LYY	880.6250	II
Polymer (Nitrile, Polyurethane, etc.)	80LZA	880.6250	II
Finger Cot	80LZB	880.6250	II
Specialty/ Chemotherapy Gloves	80LZC	880.6250	II

POWDER-FREE Patient Examination Glove Proposed Classification

Common Name	Product Code	*21 CFR Classification Number	CLASS**
Vinyl (PVC)	80LYZ	880.6251	II
Latex	80LYY	880.6251	II
Polymer (Nitrile, Polyurethane, etc.)	80LZA	880.6251	II
Finger Cot	80LZB	880.6251	II
Specialty/ Chemotherapy	80LZC	880.6251	II

(Dental, special, and chemotherapy are adjectives modifying examination -- Thus, any glove in the above list could be manufactured and labeled as a dental, special, or chemotherapy examination glove to meet the needs of users.)
* The information in this table is for gloves that meet the description in their classification regulation and, in the case of examination gloves, meet American Society for Testing and Material

(ASTM) standard D-3578, D-5250 or an equivalent standard. The ASTM standard for finger cots is D-3772. (The ASTM standard for nitrile gloves should be published in 1999.)
*** Until the effective date of a final rule reclassifying patient examinations gloves, they remain in Class I.*

Dental Examination Gloves. Gloves worn during dental cleaning, filling and the like are patient examination gloves and such gloves must meet the requirements for patient examination gloves. The term “dental” may be used in the labeling of gloves intended for dentistry. See the classification information in Table 3.1 under examination gloves. Dental examination gloves are usually “powder-free.”

Gloves used for dental surgery are surgeon’s gloves and must meet the requirements for surgeon’s gloves. The term “dental” may be used in the labeling of gloves intended for dental surgery. Gloves for dental surgery may be thicker than standard surgeon’s gloves. The labeling may contain the thickness of the gloves but ambiguous terms such as “extra thick” are not acceptable to the FDA.

SPECIALTY/ CHEMOTHERAPY GLOVES

Chemotherapy gloves are specialty medical examination gloves and require premarket notification [510(k)] clearance from FDA before marketing. Chemotherapy gloves should meet the ASTM standard D 3578 or an equivalent standard for examination gloves; however, they are usually 0.10 mm or more in thickness which is more than the 0.08 mm minimum allowed for examination gloves.

SURGEON'S GLOVES

In l999 FDA proposed in a rule in the *Federal Register* notice to reclassify surgeon's gloves into Class II Surgeon's Glove, **Powdered**, and Surgeon's Glove, **Powder-free**, because general controls are insufficient to assure their safety and effectiveness. Class II allows the use of special controls. The proposed classification regulations are as follows:

§878.4460 Surgeon's gloves, powdered.

(a) Identification. A powdered surgeon's glove is a disposable device made of natural rubber latex or synthetic material that bears powder to facilitate donning, and it is intended to be worn on the hands, usually in surgical settings, to provide a barrier against potentially infectious materials and other contaminants. The lubricating or dusting powder used on these gloves is classified separately in §878.4480.

(b) Classification. Class II special controls are as follows:

(1) Guidance document. The Center for Devices and Radiological Health, FDA, "Medical Glove Guidance Manual," as revised.

(2) Labeling. User labeling requirements in §801.440 of this chapter (i.e., 21 CFR §801.440).

§878.4461 Surgeon's gloves, powder-free.

(a) Identification. A powder-free surgeon's glove is a disposable device made of natural rubber latex or synthetic material that may bear a trace amount of glove powder and is intended to be worn on the hands, usually in surgical settings, to provide a barrier against potentially infectious materials and other contaminants.

(b) Classification. Class II special controls are as follows:

(1) Guidance document. The Center for Devices and Radiological Health, FDA, "Medical Glove Guidance Manual," as revised.

(2) Labeling. User labeling requirements in §801.440 of this chapter (i.e., 21 CFR §801.440).

Biocompatibility data for finished sterile gloves should be submitted in a 510(k) submission and also filed in the Quality System design history file per 21 CFR §820.30 to demonstrate that the gloves are safe for the intended use. Various manufacturing materials are added to latex and polymer mixtures to aid in processing, improve glove performance, improve glove stability, etc. Some of these may be adverse materials that have the potential to cause irritation, impair wound healing or other problems. Adverse manufacturing material residues that affect compromised tissue, mucous membranes or skin must be removed or limited as required by §820.3(p) and §820.70(h) of the Quality System regulation and by your labeling claims.

Surgeon's gloves must be distributed sterile. FDA will **not** accept a 510(k) for a non-sterile surgeon's glove. The shipment of medical gloves to and from a contract sterilizer is regulated under the labeling requirements in 21 CFR §801.150(e). (See Chapter 10.)

Surgeon's Gloves, Special. Surgeon's gloves with attributes for special applications with attached or integrated accessories must meet the basic regulatory requirements for surgeon's gloves as outlined above. In addition, any accessory must meet the manufacturer's labeling claims, be safe and effective (have clinical utility) and meet all other regulatory requirements. If the glove and accessory is substantially equivalent to a glove and an accessory that is already cleared for commercial distribution by the 510(k) process, then a 510(k) for the combination should be submitted to ODE. Otherwise, a Premarket Approval (PMA) may be required. Please consult with the Division of Small Manufacturers Assistance (DSMA), phone 800-638-2041, before preparing a PMA.

Table 3.2

POWDERED Surgeon's Glove Proposed Classification

Common Name	Product Code	*21 CFR Classification Number	Class ***
Surgeon's Gloves	79KGO	878.4460	II
Surgeon's Glove with/or accessory**	79KGO	878.4460	II**
Microsurgery Gloves	79KGO	878.4460	II
Orthopedic Surgeon's Gloves	79KGO	878.4460	II
Autopsy Surgeon's Gloves	79KGQ	878.4460	II
Surgeon's Gloving Cream	79KGQ	878.4470	I Exempt
Glove Liners/Undergloves	79KGO	878.4460	II
Leak Detectors & Glove Accessories	79LDQ	878.4460	II

POWDER-FREE Surgeon's Glove Proposed Classification

Common Name	Product Code	*21 CFR Classification Number	Class***
Surgeon's Gloves	79KGO	878.4461	II
Surgeon's Glove with/or accessory	79KGO	878.4461	II**
Microsurgery Gloves	79KGO	878.4461	II
Orthopedic Surgeon's Gloves	79KGO	878.4461	II
Autopsy Surgeon's Gloves	79KGQ	878.4461	II
Glove Liners/Undergloves	79KGO	878.4461	II
Leak Detectors & Glove Accessories	79LDQ	878.4461	II

* The information in Table 3.2 is for gloves that meet the description in the classification regulation and, in the case of surgeon's gloves, meet ASTM standard D 3577 or an equivalent standard.

** The accessory may have a different classification -- contact DSMA by FAX at 301-443-8818 or contact ODE by phone at 301-443-8879 for case-by-case guidance.

*** *Until the effective date of a final rule reclassifying surgeon's, they remain in Class I.*

Microsurgery Gloves. Microsurgery gloves are surgeon's gloves that meet the ASTM standard D 3577 for thickness and other parameters but are carefully processed so as to have a thickness, particularly at the fingertips, that is near the minimum allowed by ASTM D 3577. A 510(k) submission should contain all of the information applicable to regular surgeon's gloves. FDA does not accept 510(k) submissions for microsurgery gloves that are thinner than allowed by the ASTM standard.

Orthopedic Surgeon's Gloves. Orthopedic surgeon's gloves are a special form of surgeon's gloves and must meet the requirements for surgeon's gloves. Orthopedic surgical gloves may be

thicker and more resistant to tear than other surgical gloves. The thickness and other parameters of orthopedic gloves may be stated in the labeling; whereas terms such as “extra thick,” “super strong,” etc., are ambiguous and the use of such terms results in a device being misbranded. The minimum biocompatibility tests are skin irritation and dermal sensitization.

Autopsy Surgeon’s Gloves. Autopsy gloves are a special form of surgeon’s gloves intended for use during autopsy procedures and require premarket notification [510(k)] clearance from FDA before marketing. Some autopsy surgeon’s gloves may be similar to orthopedic surgeon’s gloves. Pinhole, labeling, donning powder or lubricant, protein, manufacturing material residues, and powder-free requirements for autopsy gloves are the same as for surgical gloves. The minimum biocompatibility tests are skin irritation and dermal sensitization.

GLOVE LINERS / UNDERGLOVES

Glove liners or undergloves are worn with patient examination or surgeon’s gloves, and may be made of materials such as cotton to prevent the medical glove from contacting the user’s hand or may be made of materials that are resistant to cutting or puncture. Added protection is provided by reducing the risk of a cut or puncture wound during surgical or examination procedures, absorbing perspiration, and by reducing the potential for skin irritation. Glove liners and undergloves are accessories to medical gloves and are classified the same as the gloves. Currently, they are Class I devices.

Because glove liners and undergloves contact the skin, biocompatibility data should be submitted with a 510(k) to show that they are safe for the intended use (See Chapter 5, Biocompatibility). When glove liners are made of clean, non-coated, common textiles, biocompatibility data is not needed. Manufacturers of accessories such as glove liners are required to submit a premarket notification [510(k)], register their establishment, list the glove liners, meet the medical device Quality System regulation, and properly label their glove liners. If a manufacturer claims their glove liners are leakproof, then the glove liners have to meet the ASTM acceptable quality limit (AQL) for pinholes.

SURGEON’S GLOVING CREAM

Surgeon’s gloving cream is intended to lubricate the user’s hand before putting on a surgeon’s glove. This cream may also be used with examination gloves.

Gloving cream is classified under 21 CFR 878.4470 as a Class I device. Gloving cream was exempted from premarket notification requirements by a notice in the *Federal Register,* Vol. 59, page 63010, December 7, 1994. If the intended use of the cream is different from that described in 21 CFR 878.4470, i.e., "…lubricating the user's hand…," the cream is not exempt from the 510(k) requirements.

Gloving creams should be safe and effective and should not degrade the glove material in latex or other gloves, i.e., the creams should not be oil-based. If manufacturers modify the ingredients of an existing gloving cream or introduce a new gloving cream into commercial distribution, such manufacturers are cautioned that the cream should perform as claimed, and they should have

biocompatibility data on file to show that the new or modified cream is safe for the intended use. (Medical devices including gloving cream in commercial distribution in the U.S. are never exempt from the adulteration and misbranding provisions and penalties of the FD&C Act.)

RADIOGRAPHIC PROTECTION GLOVES

Radiographic protection gloves are classified as Class I devices currently exempt from pre-market notification under 21 CFR 892.6500 as "personnel protective shield." These devices are intended to protect the operator, patient or other person from unnecessary exposure to radiation during radiological procedures by providing an attenuating barrier to radiation. The generic type of device includes articles of clothing such as gloves.

These gloves should meet the FDA or an equivalent water leak test and the minimum biocompatibility tests such as skin irritation and dermal sensitization. Manufacturers of radiographic protection gloves need to register their establishment, list the gloves, meet the medical device Quality System regulation, do medical device reporting (MDR), and properly label their gloves. In addition, manufacturers should maintain technical data to show that their attenuation claims are met for the energy range of x-rays normally used in medical procedures.

EMBALMING GLOVES

Embalming gloves are not regulated by the FDA.

FOOD HANDLING GLOVES

Gloves used for food handling or preparation are not medical devices; instead, they are considered by FDA to be a food contact surface which may result in indirect food additives to the food handled. Title 21 CFR 177.2600, *Rubber Articles Intended for Repeated Use*, lists elastomers, vulcanizing agents, accelerators, activators, coloring agents, etc., and the maximum percentages of these compounds that are permitted by FDA for use in compounding gloves for food contact.

For further information regarding additives and food use of gloves contact the:

Food and Drug Administration
Center for Food Safety and Applied Nutrition
Division of Food and Color Additives (HFF-330)
Harvey W. Wiley Federal Building, Room 1B-018, 5100 Paint Branch Parkway
College Park, MD 20740-3835
http://vm.cfsan.fda.gov/~dms/cos-toc.html

Phone: 301-436-2335 **FAX:** 301-436-2764

CLEANING AND OTHER NON-MEDICAL GLOVES

Gloves that are used for routine janitorial functions in medical facilities are not regulated by FDA. However, gloves that are used for cleaning patients, or cleaning or handling surfaces or

items contaminated with patient waste or fluids, are medical gloves and must meet the requirements for patient examination gloves.

Non-medical gloves, commonly known as utility, industrial, or general purpose gloves, are used for tasks that do **not** involve contact with patients or body fluids. Therefore, they are not regulated by the FDA.

It is illegal for manufacturers to relabel non-medical gloves for medical use or to imply in their labeling that such gloves are suitable for medical use. Companies whose names include a medical term should clearly label their industrial gloves, "For non-medical use." Be careful that the labeling does not reflect a medical logo or vignette that implies medical use.

MANUFACTURER NAME IMPLIES MEDICAL DEVICE

As mentioned above, manufacturers of household, food handling and other industrial gloves that have a medical term in their company name are requested to label their industrial gloves, "Not for medical use." Such labeling will help prevent the purchase and use of industrial gloves for medical applications.

LEAK DETECTORS

Leak detectors are chemical, electromechanical, or electronic systems designed for glove users to monitor the integrity of the glove barrier immediately before and during glove use. FDA considers these devices to be accessories to medical gloves. As such, any device labeled or intended for the medical glove user to detect leaks through the glove barrier before or during use is a medical device and requires FDA clearance before marketing. The product code for glove leak detectors or testers is 79LDQ. Leak detectors are Class I devices requiring 510(k) clearance before marketing.

Leak testers and other equipment used during the production of gloves are production equipment--not medical devices. The selection, use, control, maintenance, etc., of production equipment is covered by the QS regulation in 21 CFR §§820.70 and 820.72.