K080914

510(k) Summary

JUL 15 2008

Contact Details

Applicant Name: Rochester Electro-Medical, Inc.

4212 Cypress Gulch Dr.
Lutz, FL 33559 U.S.A.
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Charles C. Berkins, C.E.O.
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Date Prepared: July 3, 2008

Device Name

Trade Name: Ultra Sharp Concentric Needles

Common Name: EMG Needles, Concentric Needles, Bi-polar Needles

Classification Name: Electrode, needle, diagnostic, electromyograph; Diagnostic electromyography needle electrode; IKT

Legally Marketed Predicate Device(s)

510(k) Number	Product Code	Trade Name	Manufacturer
K895460	IKT	CONCENTRIC ELECTRODE TYPE #13R01, 13R02	DANTEC ELECTRONICS, INC.
931966	IKT	DANTEC DISPOSABLE CONCENTRIC NEEDLE	DANTEC MEDICAL, INC.
K924521	IKT	DISPOSABLE CONCENTRIC NEEDLE ELECTRODE	CHALGREN ENTERPRISES, INC.
K896370	GXZ	DISP. CONCENTRIC NEEDLE ELECTRODE (DCP-30, DCP-45	CHALGREN ENTERPRISES, INC.
K933795	GXZ	CONCENTRIC EMG NEEDLE ELECTRODE	CADWELL LABORATORIES, INC.
K973529	IKT	NEUROLINE, DISPOSABLE CONCENTRIC NEEDLE ELECTRODE	MEDICOTEST A/S.
K960591	IKT	RE-USABLE BIPOLAR CONCENTRIC NEEDLE(237-XXX-24,23	CHALGREN ENTERPRISES, INC.

Device Description

Bi-polar/multi-polar disposable concentric needles for recording muscle activity. The needles consist of a stainless steel hypodermic outer shell with a centered platinum/iridium inner recording core with a trocar sharpened tip. An electrically insulated molded handle incorporates the contact points allowing electrical continuity through the connecting cable, which is sold separately.

Intended Use/Indications for use

Recording muscle activity for Electromyography (EMG) applications. For Single Patient Use only. Patient population: Adults.

Substantial Equivalence Comparison

Characteristic	Predicate Devices	Rochester Device
Indications for Use	Recording muscle activity for Electromyography (EMG) applications. For Single Patient Use only.	Recording muscle activity for Electromyography (EMG) applications. For Single Patient Use only.
Target Population	Adults	Adults
Design	Outer Hypodermic shell with insulated inner recording core. Recording connections through a molded handle to a detachable connecting cable.	Outer Hypodermic shell with insulated inner recording core. Recording connections through a molded handle to a detachable connecting cable.
Materials	Stainless Steel cannula, platinum Or silver core, Molded plastic handle	Stainless Steel cannula, platinum core, Molded plastic handle
Performance	Unknown	Testing data: Core Centering & Size; Microscopic visual examination; Sharpening; Microscopic visual examination with special attention to bevel convergence, burrs and point; Electrical continuity of all poles; Electrical isolation of all poles; Needle hypodermic shell examined for straightness and stated length.
Sterility	Gamma Irradiation, E-Beam	Gamma Irradiation
Biocompatibility	Stainless Steel, Platinum & Silver	Stainless Steel & Platinum
Mechanical Safety	Packaged needle covered with a needle cover.	Packaged needle covered with a needle cover.
Chemical Safety	Not Applicable	Not Applicable
Anatomical Sites	Muscles and associated Nerves	Muscles and associated Nerves
Human Factors	Must be used by a trained, certified physician or by order of a physician	Must be used by a trained, certified physician or by order of a physician
Energy Used/Delivered	Not Applicable	Not Applicable
Compatibility with Other Devices	Compatibility is achieved through the connecting cable to EMG machines or similar physiological recording devices.	Compatibility is achieved through the connecting cable to EMG machines or similar physiological recording devices.
Where Used	Physician's office or Hospitals.	Physician's office or Hospitals.
Risk Analysis	Unknown	Risk Management completed 1-30-08 as part of the Design Control Process
Design Control	Unknown	Design Control Completed 1-30-08
Electrical Safety	Unknown	Controlled & accounted for with Risk Management.

Design Control	Unknown	Design Control Completed 1-30-08
Electrical Safety	Unknown	Controlled & accounted for with Risk Management.
Options Offered	25 mm., 30 ga. 25 mm., 26 ga. 30 mm., 28 ga. 37 mm., 26 ga. 38 mm., 26 ga. 50 mm., 26 ga. 75 mm., 23 ga.	25 mm., 30 ga. 25 mm., 28 ga. 25 mm., 27 ga. 37 mm., 27 ga. 50 mm., 27 ga. 25 mm., 26 ga. 37 mm., 26 ga. 50 mm., 26 ga. 65 mm., 25 ga. 75 mm., 23 ga.
Standards Met	Unknown	ISO 13485:2003-07-15 ISO 14971:2007-02-01 ISO 10993-1:2003 AAMI/ANSI/ISO 11137-1:2006 AAMI/ANSI/ISO 11137-2:2006 AAMI/ANSI/ISO 11137-3:2006 ISO 14644-1:1999-05-01 ISO 14644-2:2000-09-15 ISO 14644-4:2001-04-01 ISO/TR 16142:2006-01-15 BS EN 980:1996 + A1:1999 + A2:2001 ISO 9626:1991 + A1:2001 ISO 7864:1993

Non-clinical Testing

Bench Testing consisted of the following:

1. **Process Control – Used to Control the processes used in manufacturing. The methods used for verifying processes will vary depending on the process to be tested and the type of product the process is used to produce. Process Control Forms used:**
   - **Concentric Needle Sharpening – visual examination under microscope and foam test**
   - **Concentric Core Insertion – visual examination under microscope**
   - **Concentric Needle Continuity – audible ohmmeter**
   - **Concentric Needle Pole Isolation – audible ohm meter**
   - **Concentric Needle Handle Mold Design – Visual and audible ohm meter**
   - **Concentric Needle Connector Interface – Visual and audible ohm meter**
2. **Process Verification – Process verification is done according to the control process established in Process Control Forms above. Process Verification Forms used:**
   - **Concentric Needle Sharpening**
   - **Concentric Core Insertion**
   - **Concentric Needle Continuity**
   - **Concentric Needle Pole Isolation**
   - **Concentric Needle Handle Mold Design**
   - **Concentric Needle Connector Interface**
3. **Design Verification – after Process Verification has been approved, verification is performed using samples from the first production run. The methods used for the Concentric Needle Design are identical to those used in the Process Approval phase above since the process and design output parameters are the same. Design Verification Forms used:**
   - **Concentric Needle Sharpening– visual examination under microscope and foam test**
   - **Concentric Core Insertion – visual examination under microscope**
   - **Concentric Needle Continuity – audible ohmmeter**
   - **Concentric Needle Pole Isolation – audible ohmmeter**
   - **Concentric Needle Handle Mold Design – Visual and audible ohm meter**
   - **Concentric Needle Connector Interface – Visual and audible ohm meter**
4. **Standards used see comparison chart above.**

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Rochester Electro-Medical, Inc.
% Mr. Charles C. Berkins
CEO
4212 Cypress Gulch Drive
Lutz, Florida 33559

JUL 15 2008

Re: K080914
Trade/Device Name: Ultrasharp Concentric Needles
Regulation Number: 21 CFR 890.1385
Regulation Name: Diagnostic electromyograph needle electrode
Regulatory Class: Class II
Product Code: IKT
Dated: May 8, 2008
Received: May 21, 2008

Dear Mr. Berkins:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041or (240) 276-3150 or the Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K080914

Device Name: Ultra Sharp Concentric Needles

Indications for Use:

Recording muscle activity for Electromyography (EMG) applications. For single patient use only. Patient population: Adults.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative,
and Neurological Devices

510(k) Number K080914