JUN 11 2003

K030800

11 Appendix D 510(K) Summary

510(k) Summary

Submitter's Information:	Lydia Baynes Electromed 4938 Hampden Lane #750 Bethesda, MD 20814 Phone: 1-703-448-9644 FAX: 1-703-356-2182
Date of preparation:	March 11, 2003
Proprietary Name:	Electromed Reusable Neurostimulation Electrodes
Common Name:	Neurostimulation Electrodes
Classification Name:	Electrodes, cutaneous
Predicate Device:	K963125 (M & R Manufacturing, Inc.) K932849 (Pepin Mfg., Inc.)
Description of Device:	Electrodes, cutaneous
Intended Use:	Electromed Reusable Neurostimulation Electrodes are intended for use as the disposable, conductive adhesive interface between the patient's skin and the Electrical Stimulator. Electromed Reusable Electrodes are designed and intended to be used with marketed, Electrical Stimulators i.e. TENS (Transcutaneous Electrical Nerve Stimulation), EMS (Electrical Muscular Stimulation, IF (Interferential) of PGF (Pulsed Galvanic Stimulation).
Technological Comparison:	The Electromed has technological characteristics that are substantially equivalent to those of the predicate device, as determined criteria specified in the Tripartite Biocompatibility Guidance for Medical Devices.
Labeling Comparison:	The labeling of the Electromed is substantially equivalent to that of the predicate device.
Nonclinical Testing:	Bench testing demonstrated that the characteristics or Electromed are substantially equivalent to that of the predicate device.
Clinical Testing:	Not applicable.
Conclusions from Testing:	The Electromed is substantially equivalent in electrical output to the predicate device and any differences between the devices do not pose new questions of safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 11 2003

Ms. Lydia Baynes
ElectroMed, Inc.
4938 Hampden Lane #750
Bethesda, MD 20814

Re: K030800
Trade/Device Name: ElectroMed Reusable Neurostimulation Electrodes ™ sizes - 32mm round, 54x34mm, 50x90mm, 40x60mm oval, and 50x100mm oval
Regulation Numbers: 21 CFR 882.1320
Regulation Names: Cutaneous electrodes
Regulatory Class: Class II
Product Codes: GXY
Dated: March 11, 2003
Received: March 13, 2003

Dear Ms. Baynes

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.

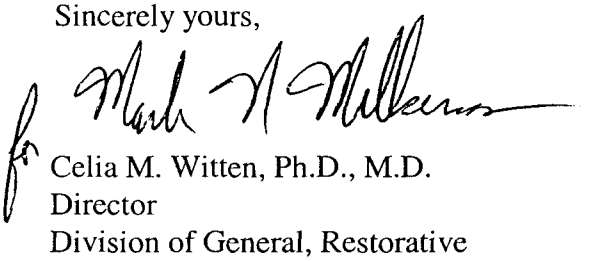
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address
http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

4 Indications for Use

510(k) Number: K030800

Device Name: Electromed Reusable Neurostimulation Electrodes™

Indications for Use:

Electromed Reusable Neurostimulation Electrodes are intended for use as the disposable, conductive adhesive interface between the patient's skin and the Electrical Stimulator. Electromed Reusable Electrodes are designed and intended to be used with marketed, Electrical Stimulators i.e. TENS (Transcutaneous Electrical Nerve Stimulation), EMS (Electrical Muscular Stimulation), IF (Interferential) of PGF (Pulsed Galvanic Stimulation).

These electrodes will include the precaution statement: Federal Law restricts this device to sale by or on the order of a physician.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N Melkerson

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

510(k) Number K030800