

OCT 22 1998

K/80410

510(K) SUMMARY

- A. **Manufacturer:** Specialised Laboratory Equipment
Limited
Twin Bridges Business Park
232 Selsdon Road
South Croydon
Surrey CR2 6PL
United Kingdom
- Submitted By:** Ferguson Medical
Consultant to Specialised Laboratory
Equipment Limited
- B. **Contact Information:** Phone: 44 181 681 1414
FAX: 44 181 649 8570
- C. **Classification Name:** Electrode, cutaneous

Common/Usual Name: Electrode, surface electrode, skin
surface electrode, stick-on
electrode, etc.

Proprietary Name: SLE Electrodes and Accessories
- D. **Classification Number:** 80GXY
- E. **Substantial Equivalence:** Electrode, PNS, NDM Corp.
(K760213), Cutaneous Electrode, Medicotest, Inc.
(K931430), Electrode, Cutaneous, Cadwell
Laboratories, Inc. (K933801), and others.
- F. **Device Description:** The SLE Electrodes and Accessories
device is a cutaneous electrode.
- G. **Intended Use:** The SLE Electrodes and Accessories
device is intended to be used in direct application
to the patient's skin to record physiological
signals including applications in EEG, EMG, nerve
conduction velocity, evoked potential, and
electronystagmography.
- H. **Technological Characteristics:** The design, materials,
chemical composition, energy source, and other
technological characteristics of the subject device
are considered to be the same as the technological
characteristics of the predicate devices.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

OCT 22 1998

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Frank Ferguson
Official Correspondent
Consultant for Specialized Laboratory Equipment Limited
Ferguson Medical
2581 California Park Drive, Suite 269
Chico, California 95928

Re: K980410
Trade Name: SLE Electrodes and Accessories
Regulatory Class: II
Product Code: GXY
Dated: July 3, 1998
Received: July 28, 1998

Dear Mr. Ferguson:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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.

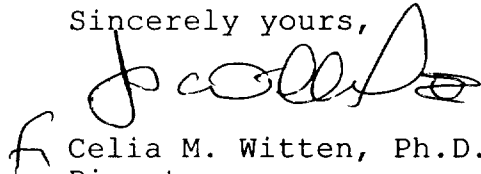
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

Page 2 - Mr. Frank Ferguson

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,

A handwritten signature in black ink, appearing to read "Celia M. Witten", with a stylized flourish at the end.

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

Enclosure

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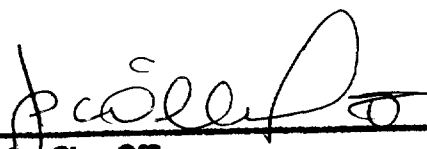
Device Name: SLE Electrodes and Accessories

Indications For Use:

SLE Electrodes and Accessories are intended to be used applied directly to a patient's skin to record physiological signals including applications in EEG, EMG, nerve conduction velocity, evoked potential, and electronystagmography.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)


(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K980410

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____

(Optional Format 1-2-96)