



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 14 2002

Medicotest A/S
c/o Ms. Emalee G. Murphy
Kirkpatrick & Lockhart LLP
1800 Massachusetts Avenue, NW
Suite 200
Washington, D.C. 20036-1221

Re: K020907

Trade/Device Name: Neuroline Subdermal Needle Electrode
Regulation Number: 890.1385 and 882.1330
Regulation Name: Diagnostic electromyography needle electrode
Depth electrode
Regulatory Class: II
Product Code: IKT and GXZ
Dated: March 15, 2002
Received: March 20, 2002

Dear Ms. Murphy:

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.

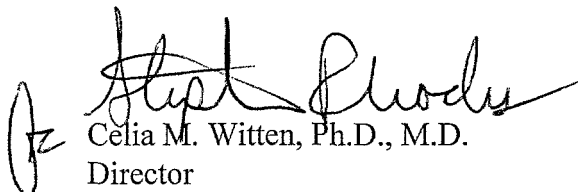
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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.

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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 and additionally 21 CFR Part 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" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained 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,

A handwritten signature in black ink, appearing to read "Celia M. Witten". To the left of the signature is a circular stamp containing the letters "CZ".

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

510 (k) Number (if known): K 020907

Device Name: Neuroline Subdermal Needle Electrode

Indications For Use:

The Neuroline Subdermal Needle Electrode is intended for use with recording, monitoring and stimulation equipment for the purpose of recording of biopotential signals for example: Electromyography (EMG), Electroencephalograph (EEG) and Nerve potentials signals. The electrodes are sterile and for single patient use only.

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

_____ Concurrence of CDRH, Office of Device Evaluation (ODE) _____

Prescription Use X OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional format 1-2-96)

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

510(k) Number K 020907