K 990015

MAY 27 1999

510(K) SUMMARY

A) Manufacturer:

Technomed Europe
Stationstraat 122
6191BG BEEK
The Netherlands

B) Submitted by:

Technomed Europe
Stationstraat 122
6191BG BEEK
The Netherlands

C) Contact information:

phone, +31 46 4 370 371
Fax, +31 46 4 379 697

D) Classification name:

Needle Electrode (21 CFR 882.1350)

E) Common/usual name:

Needle electrode EEG / EMG

F) Proprietary name:

Technomed EEG / EMG needle electrodes

G) Classification number:

89 IKT

H) Substantial Equivalence:

SLE Electrodes and accessories	K981004
Neuroline disposable concentric needle electrode	K973529
Electrode Needle diagnostic EMG	K961013
Re-useable Bipolar Concentric needle	K960591
Disposable hypodermic monopolar needle recording	K955335
Re-useable Concentric Needle electrode	K953887
Reusable monopolar Needle	K953886
Monopolar EMG needle electrode,	K933806
EEG Needle Electrode,	K933796
Electrode Needle diagnostic EMG	K912283
Detachable Disposable monopolar Needle Electrode	K912283
Disposable Monopolar Needle electrode , various models	K912282
Disposable EEG Needle Electrodes,	K901280
Monopolar needle electrode	K900098
Concentric Needle electrodes various sizes	K850107
and,...and... many more	

I) Device description:

Technomed Europe Needle electrode's and accessories consist of a variety of needle electrode's and accessories to be used for bioelectric sensing in the diagnostic field of EEG or EMG.

J) Intended use:

Technomed Europe diagnostic needle electrode's are intended to be inserted in the subdermal, muscle or nerve tissue only to sense bio-electric, EMG or EEG, signals distally, and will proximal be connected to:
Electromyography/electroencephalogram recording equipment

K) Technological Characteristics: The design, materials, chemical composition, packaging and other technological characteristics of the subject devices are considered to be the equivalent of the predicated devices.

This section is intentionally left blank, and is concluding the summary statement.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 27 1999

Mr. Harry Knuth
Manager of Operations and Regulatory Affairs
Technomed Europe
Medical Diagnostic Accessories
Stationstraat 122
P.O. Box 239
6191BG Beek
The Netherlands

Re: K990015
Trade Name: Electrode Needles
Regulatory Class: II
Product Code: IKT and GXZ
Dated: February 19, 1999
Received: February 26, 1999

Dear Mr. Knuth:

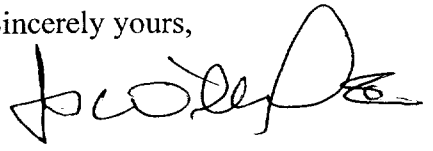
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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.

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) 594-4595. 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,



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

510(k) NUMBER (IF KNOWN): K990015

DEVICE NAME: ELECTRODE NEEDLES

INDICATIONS FOR USE:

Technomed Europe diagnostic needle electrodes are **intended** to be inserted in the subdermal, muscle or nerve tissue **to sense bio-electric, EMG or EEG, signals** distally, and are intended to be proximal be connected to electromyography / electroencephalogram recording equipment.

The intended use of the Technomed devices are consistent with Code of Federal Regulations title 21, volume 8 part 882.1350.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X (Per 21 CFR 801.109) OR Over-The-Counter-Use (Optional Format 1

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K990015