DEC - 6 1999

K990110

510 (k) SUMMARY

I. ADMINISTRATIVE

Submitter: Maersk Medical A/S
Niko Business Unit
Engmosen 1
DK-3540, Lynge
Denmark
Phone No.: 011 45 48 16 70 30

Contact Person: Mr. Christian Pelch

Date of Preparation: October 15, 1999

II. DEVICE NAME

Proprietary Name: Niko ECG Monitoring Electrodes
Common Name: ECG Electrode
Classification Name: Electrocardiograph Electrode

III. PREDICATE DEVICES

Disposable ECG Monitoring Electrode Models 4110 and 4140 (K950472); Nikomed USA, Inc.

IV. DEVICE DESCRIPTION

Pregelled electrodes are of Ag/AgCl construction with a sensor element area between 10 and 20 mm in diameter, and an adhesive part between 20 and 70 mm in diameter or rectangular/square in shape. Electrodes are bulk packaged in OPP/PE laminated pouches; 60/pouch; 300/box.

V. INTENDED USE

ECG monitoring electrodes for short-term use (< 24 hours) in adults (Model 4110) and infants (Model 4140).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC - 6 1999

Maersk Medical A/S
c/o Mr. Richard A. Hamer
Consultant to Maersk Medical A/S
Richard Hamer Associates, Inc.
P.O. Box 16598
Ft. Worth, TX 76132

Re: K990110
Disposable ECG Monitoring Electrodes
Models 4110 and 4140
Regulatory Class: II (two)
Product Code: DRX
Dated: October 15, 1999
Received: October 18, 1999

Dear Mr. Hamer:

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 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). 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 requirements, 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

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) 594-4648. 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 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/dsma/dsmamain.html".

Sincerely yours,

for

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

Enclosure

510(k) Number (if known): K990110

Device Name: Niko ECG Monitoring Electrodes Model 4110 and 4140

Indications for Use:

ECG monitoring electrodes for short-term use (< 24 hours) in adults (Model 4110) and infants (Model 4140).

(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 Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K990110

Prescription Use ✓
(Per 21 CFR 801.109)

OR

Over-the-Counter Use _____

(Optional Format 1-2 96)