

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: January 11, 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 4500 (K950473), 4530 and 4540 (K950475), 4533 (K950474), 4539 (K950480) and 4560 (K950477); 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.

VI. COMPARISON TO PREDICATE DEVICES

The Niko ECG Monitoring Electrodes are identical in composition, function and design, and have the same intended use as the legally marketed disposable ECG monitoring electrodes Models 4500 (K950473), 4530 and 4540 (K950475), 4533 (K950474), 4539 (K950480) and 4560 (K950477); Nikomed USA, Inc. Accordingly Maersk Medical A/S concluded that the Niko ECG Monitoring Electrodes Models 4500, 4530, 4533, 4539, 4540 and 4560 are safe and effective for their intended use and perform at least as well as other disposable ECG monitoring electrodes.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

DEC - 6 1999

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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: K990113
Disposable ECG Monitoring Electrodes
Models 4500, 4530, 4533, 4539, 4540 and 4560
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.

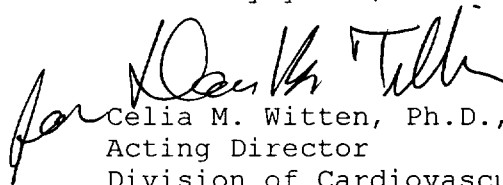
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially 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 for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

Page 2 - Mr. Richard A. Hamer

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,

A handwritten signature in black ink, appearing to read "for Celia M. Witten". The signature is written in a cursive, flowing style.

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): K990113

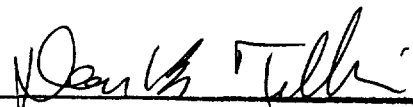
Device Name: Niko ECG Monitoring Electrodes

Indications for Use:

ECG monitoring electrodes for short term use.

(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 K990113

Prescription Use ☒
(Per 21 CFR 801.109)

OR

Over-the-Counter Use ☐

(Optional Format 1-2-96)