K022909

JAN 0 9 2003

# 510(k) Summary

**SUBMITTER:**

**Submitted on behalf of:**


| | | |
|---|---|---|
| | **Company Name:** | Nikomed U.S.A., Inc. |
| | **Address:** | 206 Airport Blvd.<br>Doylestown, PA 18901 |
| | **Telephone:** | 215-230-8455 |
| | **Fax:** | 215-230-8446 |
| **by:** | **Elaine Duncan, M.S.M.E., RAC** | President, Paladin Medical, Inc.<br>P.O. Box 560<br>Stillwater, MN 55082 |
| **Telephone:** | 715-549-6035 | |
| **Fax:** | 715-549-5380 | |


**CONTACT PERSON:** **Elaine Duncan**

**DATE SUMMARY PREPARED:** **August 26, 2002**

**TRADE NAME:** **NIKOMED TRACE 1™ ECG Electrodes**
**COMMON NAME:** **ECG Electrodes**

**SUBSTANTIALLY EQUIVALENT TO:**
All currently 510(k) cleared NIKOMED ECG Electrodes. This special 510(k) is only for labeling changes.

**DESCRIPTION of the DEVICE:**

The ECG electrode labels will have the TRACE 1™ name and will use pictographic instructions for use. This change applies to all currently marketed and any previously cleared (via premarket-notification) electrodes sold or distributed by NIKOMED USA, Inc.

**INDICATIONS FOR USE:** **No change**

**CLINICAL INFORMATION and SAFETY and EFFECTIVENESS:**

This special 510(k) just concerns labeling changes.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 0 9 2003

Nikomed U.S.A., Inc.
c/o Ms. Elaine Duncan, M.S.M.E., RAC
President
Paladin Medical, Inc.
P.O. Box 560
Stillwater, MN 55082

Re: K022909
Trade Name: Nikomed ECG Electrodes
Regulation Number: 21 CFR 870.2360
Regulation Name: Electrocardiograph Electrode
Regulatory Class: Class II (two)
Product Code: DRX
Dated: December 9, 2002
Received: December 10, 2002

Dear Ms. Duncan:

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.
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), please contact the Office of Compliance at (301) 5944646. 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) you may obtain. 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,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known) K022909

Device Name: Nikomed ECG Electrodes

**Indications for Use:**

**The Nikomed TRACE 1™ ECG Electrode is indicated for use on the body to transmit the electrical signal at the body surface to a processor that produces an electrocardiogram or vectorcardiogram. (CFR 870.2360)**

(Please Do Not Write Below This Line-Continue On Another Page If Needed)
Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____

(Optional Format 1-2-96)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K022909