K040495

APR 2 2 2004

North American Industrial
manufacturing company
4120 South Creek Rd.
Chattanooga TN 37406

www.naimco.com
Plant: 888-549-4945 Fax: 423-648-7735

510(k) SUMMARY
[as required by 21 CFR 807.92(c)]
Naimco, Inc. Iontophoresis Drug Delivery Electrodes

I. Date Prepared: February 05, 2004

II. Submitter Information

Name: Naimco, Inc.

Address: 4120 South Creek Road, Chattanooga, TN 37406

Telephone: 888-549-4945

Contact Person: Robert L. McClure, Jr. FAIC

III. Device Identification Information

Trade Name(s): Naimco, Inc. Iontophoresis Drug Delivery Electrodes

Common Name: Iontophoresis Electrode

Classification Name: Device, Iontophoresis, Other Uses

IV. Predicate Devices

The Naimco, Inc. Iontophoresis Drug Delivery Electrodes are substantially equivalent to the following legally marketed devices:

Trade Name	Manufacturer	510(k) Number
TransQe Electrodes	Iomed, Inc.	K932620
Iogel Electrodes	Iomed, Inc.	K932621
Dupel B.L.U.E. Electrodes	Empi, Inc.	K983484
Meditrode Electrodes	Life-Tech, Inc.	K882554

North American Industrial
manufacturing company
4120 South Creek Rd.
Chattanooga TN 37406

www.naimco.com
Plant: 888-549-4945 Fax: 423-648-7735

510(k) SUMMARY
[as required by 21 CFR 807.92(c)]
Naimco, Inc. Iontophoresis Drug Delivery Electrodes

V. Device Description

The Naimco, Inc. Iontophoresis Drug Delivery Electrode System consists of an active drug delivery electrode and a passive return electrode. These electrodes are designed for one use by a single patient for the local administration of ionic drug solutions into the body for medical purposes. There are multiple sizes and shapes of drug delivery electrodes to accommodate placement various sites on the body. The size of the return electrode is the same for all drug delivery electrode sizes. The Naimco, Inc. Iontophoresis Drug Delivery Electrodes have technological characteristics equivalent to those of the predicate devices, including comparable performance specifications, comparable materials including the same buffering agent (Ag/AgCl) and fiberous polyester reservoir materials on the active drug delivery electrodes and the same buffering, self-adhering polymer on the return electrode, multiple shapes and sizes of active the drug delivery electrodes, and equivalent packaging and labeling.

VI. Intended Use

Naimco, Inc. Iontophoresis Drug Delivery Electrodes are intended to be used to introduce soluble salts and other drugs into the body as an alternative to hypodermic injection.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 2 2 2004

Robert L McClure, Jr. FAIC
Quality Assurance Manager
North American Industrial Manufacturing Company
4120 South Creek Road
Chattanooga Tennessee 37406

Re: K040495
Trade/Device Name: Iontophoresis Drug Delivery Electrodes
Regulation Number: 21 CFR 890.5525
Regulation Name: Iontophoresis device
Regulatory Class: III
Product Code: EGJ
Dated: February 23, 2004
Received: February 26, 2004

Dear Mr. McClure:

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), as long as you comply with all of the Act's requirements relating to drugs labeled or promoted with the device as described below. 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 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.

Our substantially equivalent decision does not apply to the drugs that you will label or promote for use with your device. Therefore, you may neither label nor promote your device for use with specific drugs, nor package drugs with your device prior to FDA having approved the drugs for iontophoretic administration. For information on the requirements for marketing new drugs, you may contact:

Director
Division of Drug Labeling Compliance (HFD-310)
Center for Drug Evaluation and Research
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857

As you are aware, iontophoresis devices that are intended to use a direct current to introduce ions of soluble salts or other drugs into the body and induce sweating for use in the diagnosis of cystic fibrosis or for other uses, if the labeling of the drug intended for use with the device bears adequate directions for the device's use with that drug, were classified into Class II. An iontophoresis device that is intended to use a direct current to introduce ions of soluble salts or other drugs into the body for medical purposes other than those specified for class II devices is classified into Class III (21 CFR 890.5525). We published our strategy for calling for premarket approval (PMA) applications in the enclosed Federal Register, dated May 6, 1994, and the enclosed memorandum, dated April 19, 1994, and the enclosed Federal Register, dated August 22, 2000.

If you have any questions regarding this letter, you may contact:

Kevin Lee, M.D.
Food and Drug Administration
Center for Devices and Radiological Health
Division of General, Restorative and Neurological Devices
9200 Corporate Boulevard (HFZ-410)
Rockville, Maryland 20850
(301) 594-1296

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, please contact the Office of Compliance at (301) 594 – 4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification"(21 CFR Part 807.97). You may obtain other general information on your responsibilities under the Act 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,

Miriam C. Provost

for 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

Indications for Use

510(k) Number (if known): K040495

Device Name: Iontophoresis Drug Delivery Electrodes

Indications For Use:

NAImco, Inc. Iontophoresis Drug Delivery Electrodes are indicated to introduce ions of soluble salts or other drugs into the body.

Prescription Use XX AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Miriam C. Provost

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

510(k) Number K040495