K050469

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MAY 13 2005

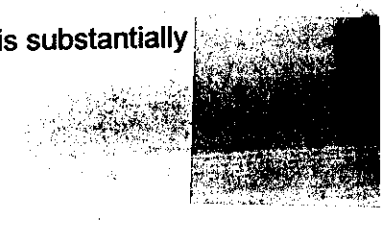
NAImco
North American Industrial manufacturing company
4120 South Creek Road
Chattanooga, TN 37406

www.naimco.com

Plant: 888-549-4945 Fax: 423-648-7735

510(k) Summary

Submitter's Information:	Robert L. McClure, Jr., FAIC NAImco, Inc. 4120 South Creek Road Chattanooga, TN 37406 Phone: 888-549-4945 Fax: 423-648-7735
Date of Preparation:	February 21, 2005
Proprietary Name:	EZ-stik Electrodes
Common Name:	Neurostimulation Electrodes
Classification Name:	Electrodes, Cutaneous
Predicate Device:	K945676 (Selective Med Components) K970426 (Axelgaard Manufacturing) K012463 (Everyway Medical)
Description of Device:	Electrodes, Cutaneous
Intended Use:	The NAImco, Inc. EZ-stik electrodes are intended for use as a disposable, conductive adhesive interface between the patient's skin and the Electrical Stimulator. NAImco's reusable electrodes are designed and intended to be used with marketed, Electrical Stimulators, i.e. TENS (Transcutaneous Electrical Nerve Stimulation), EMS (Electrical Muscular Stimulation), IF (Interferential) or PGF (Pulsed Galvanic Stimulation).
Technological Comparison:	The NAImco, Inc. EZ-stik electrodes exhibit technological characteristics that are substantially equivalent to those of the predicate device, as determined by both component usage and physical testing.
Labeling Comparison:	The labeling of NAImco, Inc. EZ-stik electrodes is substantially equivalent to those of predicate device.



Non-clinical Testing:	The (critical) components used in NAImco, Inc. EZ-stik electrodes (Amgel 703 or Amgel 702 and Conductive Plastic Film) are the same as used in the predicate device. Therefore there is no reason to believe that the NAImco, Inc. EZ-stik electrodes will perform any different than the predicate device.
Clinical Testing:	Not Applicable
Conclusions:	The NAImco, Inc. EZ-stik electrodes are substantially equivalent to those of predicate device and any difference between the devices do not pose new questions of safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 13 2005

Mr. Robert L. McClure
Naimco, Inc.
4120 South Creek Road
Chattanooga, Tennessee 37406

Re: K050469
Trade/Device Name: EZ-Stik Electrodes
Regulation Numbers: 21 CFR 882.1320
Regulation Names: Cutaneous electrode
Regulatory Class: II
Product Code: GXY
Dated: May 2, 2005
Received: May 6, 2005

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) 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 (240) 276-0120 . 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 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/industry/support/index.html.

Sincerely yours,

Miriam Provost, Ph.D.
Acting 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): K050469

Device Name: **EZ-Stik Electrodes**

Indications For Use: **The NAlmco, Inc. EZ-stik electrodes are intended for use as a disposable, conductive adhesive interface between the patient's skin and the Electrical Stimulator. NAlmco's reusable electrodes are designed and intended to be used with marketed, Electrical Stimulators, i.e. TENS (Transcutaneous Electrical Nerve Stimulation), EMS (Electrical Muscular Stimulation), IF (Interferential) or PGF (Pulsed Galvanic Stimulation).**

Prescription Use ✓ 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 In Vitro Diagnostic Devices (OIVD)

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

510(k) Number K050469