510(k): k092546

510(k) Summary

DEC 18 2009

This summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of 21 CFR Part 807.92.

Date: July 18, 2009

1. Company and Correspondent making the submission:

Name – GMDASZ Manufacturing Co., Ltd.

Address – E-1308, Xihaimingzhu Building,

Nanshan District, Shenzhen City

Guangdong Province, China

Telephone – +86 755 86250965

Fax – +86 755 26669658

Contact – Xiangjie Zhang

Email – gmdasz@188.com

2. Device :

Trade/proprietary name: GMDASZ TENS Electrodes

Common Name : Cutaneous electrode

Classification Name : electrode, cutaneous

Predicate Devices:

Predicate Model	Manufacturer	K Number	Submitted Device
ValuTrode	Axelgaad Manufacturing Co., Ltd	K970426	GMDASZ TENS Electrodes
EZ-Stik	NAImco, Inc.	K050469	GMDASZ TENS Electrodes

3. Classifications Names & Citations :

21CFR 882.1320, GXY, Cutaneous Electrode

4. Description :

4.1 General

GMDASZ TENS electrodes are multi-layer reusable, flexible structures composed of laminated materials commonly used in this application (Refer to attached BOM):

First layer—insulating backing material: Fabric, foam or tan fabric
Second layer—Conductive plastic film
Third Layer—Biocompatible self-adhesive conductive hydro gel
Protective liner—PET

The electrodes are designed for single-patient/ multiple application use. Because of the adhesive nature of the biocompatible conductive hydro gel, no securing materials are required to secure the device to the patient's skin. The electrode is connected to the stimulating device by lead wire, with a standard .080" recessed female terminal with insulating outer jacket. By design, the insulated outer jacket prevents the conductive connection to earth or hazardous voltages as required in IEC60601-1 Subclause 56 3(c). Wire assembly is incompliance with FDA performance standard 21 CFR Part 898.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

GMDASZ Manufacturing Co., LTD
c/o Mr. Charlie Mack
Principal Engineer
International Regulatory Consultants, LLC
77325 Joyce Way
Echo, Oregon 97826

DEC 18 2009

Re: K092546
Trade/Device Name: GMDASZ TENS ELECTRODES, Models CWN1005, CWN1007, CWN2505, CWN2509, ACWN1005, ACWN1007, ACWN2505, ACWN2509
Regulation Number: 21 CFR 882.1320
Regulation Name: Cutaneous Electrode
Regulatory Class: II
Product Code: GXY
Dated: November 28, 2009
Received: December 7, 2009

Dear Mr. Mack:

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 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/cdrh/mdr/ for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Tessa Alexander for

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological,
and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K092546

Device Name: GMDASZ TENS Electrodes

Indications for Use:

The GMDASZ TENS Electrodes are intended for use as a reusable, conductive adhesive interface between the patient's skin and the Electrical Stimulator. GMDASZ'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).

The electrotherapy electrodes are intended to be used to apply electrical stimulation current to the patient's skin.

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Ophthalmic, Neurological and Ear, Nose and Throat Devices

510(k) Number K092546