AXELGAARD
MANUFACTURING CO., LTD.

005_510K_Summary_ValuTrode_7_13_13

JUL 1 7 2013

510(k) Summary K130987
807.92(c)

Submitter/Contact Person

Dan Jeffery, President
Axelgaard Manufacturing Co., Ltd.
520 Industrial Way
Fallbrook, CA 92028
Phone: 760-451-8000 Fax: 760-723-2356
Dan.jeffery@axelgaard.com

Device Identification

Common Name:	Electrodes, Cutaneous
Trade Name/Common Name:	ValuTrode® Neurostimulation Electrodes
Regulation No.:	21CFR 882.1320 Electrodes, Cutaneous
Classification:	Class II
Product Code:	GXY

Device Description (807.92[a] [4])

The ValuTrode® reusable self-adhering electrode is used as a transcutaneous electrical nerve stimulation electrode in conjunction with an electrical stimulator for TENS or EMS.

Technical Characteristics

The device functions as a passive device by carrying an electrical signal from a neurostimulation device through the device cable and electrode lead wire to the user skin. It is composed of a cover, connector lead wire, or snap, conductive carbon film, conductive hydrogel, and an electrode carrier liner. Proper current distribution is delivered via a connector lead wire stripped to an additional length, or use of a printed silver pattern.

Everyway Medical manufactures the Lifecare Electrode (K083302) with the same conductive hydrogel, conductive carbon film and electrode carrier liner as Axelgaard's ValuTrode Neurostimulation Electrodes. Axelgaard Manufacturing supplies these components to Everyway.

Intended Use (807.92[a] [5])

ValuTrode® reusable, self-adhering, over-the-counter Neurostimulation Electrodes are indicated for use with transcutaneous electrical stimulation devices. Some common types of transcutaneous stimulation devices include, but are not limited to, transepithelial nerve stimulation (TENS) and electrical muscle stimulation (EMS) devices. Transcutaneous Neurostimulation Electrodes are passive devices serving as an interface between a user's skin and a neurostimulation device.

Legally Marketed Predicate Devices (807.92[a] [3])

Device Name	Manufacturer	510(k) No.	Date Cleared
Life Care Electrodes	Everyway Medical Instruments Company	K083302	2009
ValuTrode® Neurostimulation Electrodes	Axelgaard Manufacturing Co., Ltd.	K970426	1997

(The Substantial Equivalency Summary and subsequent pages are formatted in landscape orientation for ease of reading.)

Substantial Equivalence Summary (807.92[a] [6])

	Subject Device Axelgaard ValuTrode OTC (K130987)	Everyway Lifecare (K083302)	Axelgaard ValuTrode (K970426)
Technology	Cutaneous electrode which conducts an electrical signal from a neurostimulation device through a leadwire; which is dispersed from the wire across a conductive surface; then transmitted through the conductive adhesive gel to the surface of the patient's skin.	Cutaneous electrode which conducts an electrical signal from a neurostimulation device through a leadwire; which is dispersed from the wire across a conductive surface; then transmitted through the conductive adhesive gel to the surface of the patient's skin. The electrode connection point (leadwire) is compatible with standard, marketed Neurostimulation devices. The device is safe and effective as the predicate devices cited (within their 510(k) submittal.	Cutaneous electrode which conducts an electrical signal from a neurostimulation device through a leadwire; which is dispersed from the wire across a conductive surface; then transmitted through the conductive adhesive gel to the surface of the patient's skin.
Safety & Effectiveness	**Safety & Effectiveness-** Based on successful biocompatibility testing of the skin contacting conductive hydrogel, the electrical performance of the insulated leadwire components and electrode current distribution test results, the ValuTrode neurostimulation devices are safe and effective when used as an interface between a user's skin and an approved neurostimulation devices. Our labeling states: "Consult electrode manual for proper electrode size. Do not exceed 0.1watts/cm^2." **FDA max power guidelines draft guidance 2010 states in Section D.(vi) a maximum average power density that does not exceed .025 watts per square centimeter of electrode conductive surface area.**		**Safety & Effectiveness-** Based on successful biocompatibility testing of the skin contacting conductive hydrogel, the electrical performance of the insulated leadwire components and electrode current distribution test results, the ValuTrode neurostimulation devices are safe and effective when used as an interface between a user's skin and an approved neurostimulation devices. **See FDA comment below:** "All leadwire connectors are safety protected with insulated shrink wrapping. Cables are not supplied with the device. Maximum energy density was calculated for the smallest electrode size using an average current of 30 mA (90 or 60 mA, with duty cycles of 33 and 50 percent, respectively) across a 2 Kohm resistance and found the power to be 0.10 W/cm^2 well below the limit conservatively established for thermal burns. The manufacturer has added a prominent statement to the labeling not to exceed 0.1 watts/cm^2.'" **John Francis Glass, FDA Biologist K970426 submittal reviewer, 5/8/1997.**

	Subject Device Axelgaard ValuTrode OTC (K130987)	Everyway Lifecare (K083302)	Axelgaard ValuTrode (K970426)
Features / Materials	Four basic components: ▪ Top cover material ▪ Lead wire or snap connection ▪ Lead wire has insulation on female connector ▪ Conductive carbon film ▪ Conductive hydrogel	Four basic components: ▪ Top cover material ▪ Lead wire connection ▪ Lead wire has insulation on female connector ▪ Conductive carbon film ▪ Conductive hydrogel	Four basic components: ▪ Top cover material ▪ Lead wire or snap connection ▪ Lead wire has insulation on female connector ▪ Conductive carbon film ▪ Conductive hydrogel
Indications of Use Principles of Operation	ValuTrodes® are intended for use with Transcutaneous Electrical Neurostimulation (TENS) units as over the counter devices. Some common type of neurostimulation devices include, but are not limited to, TENS and EMS devices. Transcutaneous Electrical Neurostimulation electrodes are passive devices serving as an interface between a users' skin and a neurostimulation device.	Electrodes are intended for use with transcutaneous neurostimulation devices as over the counter devices. Some common type of neurostimulation devices include, but are not limited to, TENS and EMS devices. Transcutaneous neurostimulation electrodes are passive devices serving as an interface between a patient's skin and a neurostimulation device.	ValuTrodes™ are intended for use with FDA approved Transcutaneous Electrical Neurostimulation (TENS) devices. Transcutaneous Electrical Neurostimulation electrodes are passive devices serving as an interface between a patient's skin and a neurostimulation device.
Differences	ValuTrode® electrodes will offer lead wire and snap connection configurations Change in product labeling only to allow the product to be sold for over-the-counter. We claim that these electrodes can be sold as OTC (over-the-counter) under the 510(k) regulation (21 CFR 801 Subpart C) requiring 510(k) submittal.	The Lifecare Electrode 510(k) only offers lead wire connection electrodes. Lifecare Electrodes are sold as over-the-counter devices.	ValuTrode™ electrodes offer lead wire and snap connection configurations The devices are currently being sold as prescription medical devices.

Performance Data

No performance data is required to support this submission since the proposed over-the-counter ValuTrode® Neurostimulation Electrode has identical technological characteristics (including design and materials) as compared to the currently marketed predicate ValuTrode® Stimulation Electrode (K970426). This pre-market notification supports a change to the product labeling only to allow the product to be sold for over-the-counter use.

Safety / Effectiveness and Conclusion Statement (860.7)

Axelgaard Manufacturing Co., Ltd. considers the ValuTrode® over-the-counter Neurostimulation electrode to be as safe and effective as the predicated device Lifecare Electrode K083302 noted above.

Based upon an evaluation of the labeling proposed and the Lifecare and Axelgaard Manufacturing ValuTrode® electrodes, Axelgaard Manufacturing Co., Ltd. believes that the proposed **ValuTrode®** self adhering reusable **Neurostimulation Electrode** is suitable for over-the-counter under the 510(k) regulation (21 CFR 801 Subpart C) requiring 510(k) submittal.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

July 17, 2013

Axelgaard Manufacturing Co., Ltd.
C/O Dan Jeffery, President
520 Industrial Way
Fallbrook, CA 92028

Re: K130987
Trade/Device Name: ValuTrode® Neurostimulation Electrodes
Regulation Number: 21 CFR 882.1320
Regulation Name: Electrodes, Cutaneous
Regulatory Class: Class II
Product Code: GXY
Dated: April 4, 2013
Received: April 19, 2013

Dear Mr. Jeffery:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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 contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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/MedicalDevices/Safety/ReportaProblem/default.htm 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 (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Victor Krauthamer -S

Victor Krauthamer, Ph.D.
Acting Director
Division of Neurological
And Physical Medicine Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): **K130987**

Device Name: **ValuTrode® Neurostimulation Electrodes**

Indications For Use:

ValuTrode® reusable, self-adhering, over-the-counter Neurostimulation Electrodes are indicated for use with transcutaneous electrical stimulation devices. Some common types of transcutaneous stimulation devices include, but are not limited to, transepithelial nerve stimulation (TENS) and electrical muscle stimulation (EMS) devices. Transcutaneous Neurostimulation Electrodes are passive devices serving as an interface between a user's skin and a neurostimulation device.

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Victor Krauthamer -S
2013.07.18 11:42:08 -04'00'

(Division Sign Off)
Division of Neurological and Physical Medicine Devices (DNPMD)

510(k) Number **K130987**