K113375

eSWALLOW® USA

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JAN 25 2013

510(k) Summary

This summary of information is being submitted in accordance with the requirements of SMDA 1990 and CFR 807.92.

510[k] Owner's Name	eSWALLOW USA, LLC
Address:	106 Hidden Drive Scottsboro, Alabama 35769
Phone:	256-571-0443
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Contact:	William R. Ingram, Managing Principal
Summary Date:	January 18, 2013

Trade Name: eSWALLOW USA Electrodes and Leadwire

Common Name: Cutaneous electrode; leadwire for connection of cutaneous electrode

Classification Name: 21 CFR 882.1320, Cutaneous Electrodes

Classification: Class II

Legally marketed device to which equivalence is claimed [Predicate Device]: K083756, SpectraMed, Inc. Guardian 150 electrode

Description of Electrodes / Leadwire

The devices are single patient, multiple-use [up to three times] cutaneous electrodes for the application of electrical stimulation. The lead wire is attached to the electrode and is designed to be connected to a transcutaneous external muscle stimulator. The cutaneous electrodes are available in two sizes; one for adult patients and one for youth patients. Both sizes are composed of identical materials.

The cutaneous electrodes and lead wire do not contain active electronics, software or firmware. The lead wire connects to the cutaneous electrode to the electrotherapy device.

The cutaneous electrodes are composed of materials commonly used in this application: polyethylene, medical grade adhesives, 'spunlace' non-woven, carbon film, silver, polyester, and hydrogel.

Indications for Use

The electrodes and lead wires are intended for muscle reeducation by application of external stimulation to the muscles necessary for pharyngeal contraction.

Comparison to Predicate Device

Many devices for external, transcutaneous electrotherapy have been cleared by FDA for multiple intended uses. In this submission only the electrodes and lead wires to be used with a previously cleared NMES device are described.

Summary Comparison Table of New Device to Predicate Device

Parameter	Device	Predicate Device
Device Name	eSWALLOW USA Electrodes and Leadwire	Guardian 150 Electrode
Manufacturer	Pepin Manufacturing, Inc.	SpectraMed [originally cleared by SelectiveMed Components, Inc.]
510[k] #	K113375	K083756
Class	II	Same
21 CFR number	882.1320	Same
Code	GXY	Same
Product Type	Cutaneous electrodes / lead wires	Same

Parameter	Device	Predicate Device
Description	Single-patient, multiple-use, self-adhering, disposable electrodes and lead wires	Same
To be used with	NMES Device	Same
Intended Use	For application of electrical current to patient skin	Same
Indications for Use	For muscle reeducation by application of external stimulation to the muscles necessary for pharyngeal contraction	Same
End User; setting	Healthcare personnel; office setting and home use	Same
Body Site	External, anterior pharyngeal region	Same
Mode of Action	Electrotherapy	Same
Standards met	ANSI/AAMI EC12:2000/[R] 2010	Same
Pt-contacting Materials	Biocompatible per ISO 10993	Same
Component materials	Polyethylene, medical grade adhesives, spunlace, carbon film, silver, polyester, and hydrogel	Silver / silver chloride carbon conductor; proprietary blue hydrogel, medical grade adhesives
Sterility	Non-sterile	Same
Electrode size, shape	Adult: 0.85 inch round electrode; pediatric: 0.688 inch round electrode; adhesive butterfly shape; round lead wires with snap connectors	Adult: 0.875 inch round electrode; pediatric: 0.6875 inch round electrode; adhesive butterfly shape; round lead wires with snap connectors
Packaging	Sealed pouch	Same

Bench Testing

Biocompatibility of the patient-contacting materials was demonstrated by the source manufacturer per ISO-10993 for cytotoxicity, primary skin irritation, and delayed contact hypersensitivity, per FDA G-95 requirements for skin-contact devices of limited duration use.

Testing of the electrodes and lead wires was done by the contract manufacturer per ANSI/AAMI EC12:2000/[R] 2010, Disposable ECG Electrodes, for impedance and dispersion testing.

Clinical Testing

No clinical studies were required for electrodes and lead wires. The electrotherapy device with which these electrodes and lead wires are used was previously cleared under K092202.

Device Comparison Statement

The eSWALLOW electrodes and lead wire have the same intended use and indications for use as the predicate device. The electrodes and lead wires are made of the same biocompatible materials and have similar technological characteristics as previously cleared devices and therefore raise no new issues of safety. Based on the assessment of performance data and the characteristic comparison, the eSWALLOW electrodes and lead wire are substantially equivalent to the legally marketed predicate device.

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

January 25, 2013

eSwallow™ USA, LLC
c/o Mr. William R. Ingram
Managing Principal
106 Hidden Drive
Scottsboro, Alabama 35769

Re: K113375
Trade/Device Name: eSwallow USA Electrodes and Lead Wires
Regulation Number: 21 CFR 882.1320
Regulation Name: Cutaneous Electrode
Regulatory Class: Class II
Product Code: GXY
Dated: November 1, 2012
Received: December 3, 2012

Dear Mr. Ingram:

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 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/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,

Joyce M. Whang

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): K113375

Device Name: eSWALLOW USA Electrode and Lead Wires

Indications For Use:

For muscle reeducation by application of external stimulation to the muscles necessary for pharyngeal contraction.

Prescription Use X 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 IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Joyce M. Whang

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

510(k) Number K113375