510(k) SUMMARY

K092202

FEB 10 2011

eSWALLOW™ USA

Device: eSWALLOW™ Dysphagia Therapy Unit

Date Prepared	February 9, 2011
Summary prepared by:	William H. "Bill" Ingram, President
Applicant	eSwallow USA
Device Name	Dysphagia Therapy Unit
Trade Name	eSWALLOW™ USA 3477 Creek Circle Guntersville, AL 35976 Phone: 256-571-0443 Toll Free: 866-964-3102 Sales: 800-455-3101 FAX: 256-571-7539
Common Name	Electrical Stimulator
Classification	Class: II Product Code: IPF Regulation: 21 CFR 890.5850
Identification of Predicate Devices and Summary of Substantial Equivalence	The eSWALLOW™ Dysphagia Therapy Unit is substantially equivalent with respect to intended use, design, risks, device characteristics and performance aspects to: Vital Stim, K023347, CHATTANOOGA GROUP
Device Description	This device is a dual channel battery operated electrical stimulator for use with skin surface electrodes. The output current in each channel can be adjusted from 0-25 ma in 1 ma increments. The pulse repetition rate is fixed at 80 Hz. The output waveform is bipolar symmetrical constant current.

Intended Use and Indications	This device is intended for muscle re-education by application of external stimulation to the muscles necessary for pharyngeal contraction.
Technological Characteristics and Substantial Equivalence	The eSWALLOW™ Dysphagia Therapy unit has many similar technological characteristics and is substantially equivalent to the predicate. The method of use for the eSWALLOW™ device is exactly the same as the predicate. The materials used in the eSWALLOW™ are also similar to those used in the predicate. Both devices use an electronic circuit board mounted inside a plastic box. Both units are powered by alkaline batteries. Both units use constant current sources and have nearly identical pulse widths, intensities, and open circuit voltages. The output circuit design provides a constant current source allowing for variations in electrode resistances.
Performance Testing/Data	Tests were performed on the device which demonstrated that the device performs comparably to and is substantially equivalent to the predicate device. Tests include: Electrode resistance, output accuracy, Software Validation, and EMC compatibility testing.
Conclusion	Because the technological characteristics and intended use are nearly identical to the predicate device (including pulse type, rate, and output) we have determined that the eSWALLOW™ device is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

FEB 10 2011

eSWALLOW™ USA
% Kamm & Associates
Mr. Daniel Kamm, P.E.
8870 Ravello Court
Naples, Florida 34114

Re: K092202
Trade/Device Name: eSWALLOW™ Dysphagia Therapy Kit
Regulation Number: 21 CFR 890.5850
Regulation Name: Powered muscle stimulator
Regulatory Class: Class II
Product Code: IPF
Dated: December 8, 2010
Received: December 14, 2010

Dear Mr. Kamm:

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,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
And Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): K092202

Device Name: eSWALLOW™ Dysphagia Therapy Kit

This device is intended for muscle re-education 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 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K092202