510(k) Summary per 21 CFR 807.92(c)

510(k) # K070425

SUBMITTER:	Chattanooga Group, A Division of Encore Medical, L.P. 4717 Adams Road Hixson, TN 37343
ESTABLISHMENT REGISTRATION:	1022819
CONTACT:	Michael Treas, Manager of Regulatory Affairs
DATE PREPARED:	May 31, 2007
PROPRIETARY NAME:	Vitalstim Experia
MODELS:	5950, 5951
CLASSIFICATION:	Class II
PRODUCT CODES:	IPF, HCC
REGULATION NUMBERS AND COMMON NAMES:	21 CFR 890.5850- Stimulator, Muscle, Powered 21 CFR 882.5050- Biofeedback device
PANEL:	Physical Medicine

JUN 11 2007

Description:

Vitalstim Experia therapy is a comprehensive electrotherapy device for treating patients suffering from dysphagia. It is a prescription device administered to patients by or under the direction of a licensed healthcare provider in hospitals, post acute care facilities, nursing homes and outpatient clinics. The intended use is achieved by the benefit of powered muscle stimulation and muscle activity biofeedback in one comprehensive device. The intended patient outcome is to regain control of muscles to swallow food without aspirating.

Indications for Use:

Muscle re-education by application of external stimulation to the muscles necessary for pharyngeal contraction.

Intended Uses:

VitalStim™ waveform is a square symmetrical biphasic waveform with interphase interval pulse with the application for use on the swallowing musculature in the anterior portion of the neck.
The intended uses are:
The VitalStim waveform intended uses are muscle re-education of the swallowing musculature in the treatment of dysphagia (swallowing problems) from any etiology except mechanical causes that would need surgical intervention (for instance, obstructing tumors). Non-mechanical causes of dysphagia include: neurological and muscle disorders; cardiovascular accidents; respiratory disorders with swallowing complications; iatrogenic conditions (conditions caused by surgery); fibrosis/stenosis arising from radiation; disuse due to stroke, intubation, or birth-related anoxic injuries; and trauma to the head and neck. This device is a prescription device intended for use by or on the order of a physician or other licensed health professional.

VMS™ waveform is a square symmetrical biphasic waveform with the application for use on the musculature of the face.
The intended uses are:
Optional application of sEMG biofeedback with Muscle Stimulation VMS™ waveform for prevention or retardation of disuse atrophy, for muscle re-education, and for relaxation of muscle spasms in the treatment of swallowing musculature dysfunction in post-traumatic conditions or after neurological insult with impaired neuromuscular function.

HVPC™ waveform is a very brief pulsed monophasic waveform with the application for use on the musculature of the face.
The intended uses are:
Optional application of sEMG biofeedback with Muscle Stimulation High Volt Pulsed Current (HVPC) waveform for prevention or retardation of disuse atrophy, for muscle re-education, and for relaxation of muscle spasms in the treatment of swallowing musculature dysfunction in post-traumatic conditions or after neurological insult with impaired neuromuscular function.

sEMG™ is surface biofeedback for use on the swallowing musculature of the face and/or anterior portion of the neck.
The intended uses are:
The sEMG intended uses are surface electromyography biofeedback for relaxation training and muscle re-education.

Substantially Equivalent Predicate Devices

510(k) #	*Proprietary Name*	*Device Classification Name(s), Regulation Number(s), Classification(s) and Product Code(s).*
K023347	Chattanooga Vitalstim	Stimulator Muscle Powered, 890.5850, Class II, IPF
K002410	Freed Bioelectric	Stimulator Muscle Powered, 890.5850, Class II, IPF
K053266	Myotrac Infiniti	Stimulator Muscle Powered, 890.5850, Class II, IPF Biofeedback Device, 882.5050, Class II, HCC
K972997	AM800 Automove with EMG	Stimulator Muscle Powered, 890.5850, Class II, IPF Biofeedback Device, 882.5050, Class II, HCC

Accessories: The Vitalstim Experia utilizes special patented patient electrodes and lead wires with indexed connectors to ensure proper connection for intended use. The uniqueness of the electrodes is in the convenient patented snap type connection for attaching to the patient lead wires, as well as their unique small size for use in the anterior portion of the neck.

Certification Program: The VitalStim dysphagia therapy certification program is recommended for healthcare providers prior to administering VitalStim dysphagia therapy. The Vitalstim certification program educates the healthcare professional on the indications, contraindications and the importance of electrode placement. It is recommended that only VitalStim electrodes be used with the Vitalstim Experia therapy device. Any supplemental electrodes must be cleared to market by the FDA specifically for use in the anterior portion of the neck, and for use with the Vitalstim Experia therapy device.

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Declarations of Conformity

The Vitalstim Experia device is in compliance with the following FDA recognized Consensus Standards:

UL 60601-1: 2003, Standards for Medical Equipment Part 1: General Requirements for Safety, 1st Edition

IEC 60601-1-2: 2001, Medical Electrical Equipment Part 1 – 2: General requirements for Safety - Collateral Standard, Electromagnetic Compatibility – Requirements and Tests, 2nd Edition

Truthful and Accurate Statement

A statement attesting to the truthfulness and accuracy of the information was included in the premarket submission.

Further Information

In the event that additional information is required, please contact:

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Chattanooga Group
% Mr. Michael Treas
Manager of Regulatory Affairs
4717 Adams Road
Hixson, Tennessee 37343

JUN 11 2007

Re: K070425
Trade/Device Name: Vitalstim Experia
Regulation Number: 21 CFR 890.5850
Regulation Name: Powered muscle stimulator
Regulatory Class: II
Product Code: IPF, HCC
Dated: April 30, 2007
Received: May 2, 2007

Dear Mr. Treas:

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

Sincerely yours,

Mark N. Melkerson
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: K070425

Device Name: VitalStim Experia

Indications for Use:

"Muscle re-education by application of external stimulation to the muscles necessary for pharyngeal contraction."

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

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

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