FEB 7 2013

510(k) Summary K120922

1- Date summary prepared: December 23, 2012

2- Owner/submitter/applicant/sponsor information:

FDA Registration # 1528764
SELECTIVE MED™ COMPONENTS, INC
504 Harcourt Road Suite D
Mount Vernon, Ohio 43050
Tel 740-397-7838. Fax 740-397-6112
Contact name: Mr Richard Fisher III, President

3- Device information:

Common/usual/classification name: Powered Muscle Stimulator
Device name: Guardian Dysphagia dual channel NMES unit (abbreviation: lithe Guardian")
FDA 3 letter code IPF, FDA regulation number: 21 CFR: 890.5850
Regulation medical specialty Physical Medicine, Class 2

4- Substantial equivalency is claimed against the following predicate device(s):

510k number Trade or Proprietary or Model Name Manufacturer: K070425 Chattanooga VitalStim Experia Chattanooga Group, a division of Encore Medical

5- Description of the device:

Guardian Dysphagia dual channel NMES is a lightweight battery powered dual channel neuromuscular stimulation device used 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 patient outcome is to regain control of muscles used to swallow food and drink liquids without aspirating.

It is to be used with Guardian 150 electrode or other compatible electrodes cleared for the same indications for use, as well as lead wires.

6- Intended use {Indications for use:

This device is intended/ indicated for use for Muscle re-education by application of external stimulation to the muscles necessary for pharyngeal contraction

7- Basis for a determination of substantial equivalency (comparison table)

Characteristic	Predicate K070425 Chattanooga VitalStim Experia	K120922, Guardian Dysphagia Dual Channel NMES
Output configuration	Dual Channel, electrically Isolated with miniature safety connectors	SAME
Output waveform	AC Mode: Rectangular symmetrical biphasic with zero net DC	SAME
Regulated current or voltage	Constant current	Constant current
Patient voltage	100 Volts max, no load	SAME
Automatic overload trip	For high resistance the circuit detects this and shuts off the current. The current indicator shows this by flashing "0". Trip point measured: 33 k ohm. Can withstand permanent short or open circuit	SAME. Trip point measured: 23 k ohm. Can withstand permanent short or open circuit

Characteristic	Predicate K070425 Chattanooga VitalStim Experia	K120922, Guardian Dysphagia Dual Channel NMES
Intensity Control	Dual intensity potentiometers: 0-25 mA peak current output, adjustable current. Constant current regulation from 0 to 4000 ohms load minimum	SAME
Pulse Rate	Fixed, 80 Hz	SAME
Pulse shape	Positive square wave of 300 µs width followed by an interphase interval of 100 µs followed by a negative square wave of 300 µs width symmetric in shape and amplitude to that of the positive square wave (and therefore charge balanced).	Positive square wave of 300 µs width followed by an interphase interval of 100 µs followed by a negative square wave of 300 µs width symmetric in shape and amplitude to that of the positive square wave (and therefore charge balanced).
Low battery indicator display	LCD symbol	LCD Symbol: Triggers at 6.6 volts
Ramp down/ramp up and rest time.	Down: 0.75 s. Up: 0.75 s. Off: 1.0 s	Down: 0.75 s. Up: 0.75 s. Off: 1.0 s
Rest Period:	Each 57.5 seconds of operation, the unit will reduce power down to zero power for a period of 1 second. The power ramps down to zero and back up to the preset power over a total time of 2.5 seconds	Each 57.5 seconds of operation, the unit will reduce power down to zero power for a period of 1 second. The power ramps down to zero and back up to the preset power over a total time of 2.5 seconds
Distance between electrodes	30 mm	30 mm
Electrode dimensions	Conductive area: 0.75" round. 19 mm x 2 contacts)	105 x 55 mm with liner, 74 x 36 mm fabric, Conductive area: 0.875" diameter round, 2 contacts. (22.5 mm diameter) silver film/gel (round, x 2) (K083756)
Electrode conductive surface area	Surface area of 0.882 sq. In. for two electrodes	Surface area of 1.14 sq. In. for two electrodes
Additional characteristics		
Timer	60 minutes	60 minutes
Pulse width	300 µ sec	300 µ sec
Pulse current range	0-25 ma	0-25 ma
Number of independent channels	2	2
Power source	2 AA cells	9 Volt Alkaline battery
Start up current	Not specified	Zero ma.

8- Non-clinical test discussion: Bench testing consisted of:

Electrical Safety in accordance with IEC 60601-1
EMC Testing in accordance with IEC 60601-1-2
Oscillometric testing in accordance with FDA Recommendations for Electrical Stimulators, Software/Hardware Validation, Risk Analysis according to ISO 14971:2007 and FDA's Guidance for 510(k)s for Devices Containing Software (2005).

9- Clinical test discussion: Not applicable/not required.

10- Conclusion: In reviewing the table above and the test results, we conclude that our device is substantially equivalent based on technological characteristics, construction, and indications for use.

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

February 7,2013

SelectiveMed™ Components, Incorporated
% Mr. Daniel Kamm
8870 Ravello Court
Naples, Florida 34114

Re: K120922
Trade/Device Name: Guardian Dysphagia Dual Channel NMES
Regulation Number: 21 CFR 890.5850
Regulation Name: Powered muscle stimulator
Regulatory Class: Class II
Product Code: IPF
Dated: January 22, 2013
Received: January 30, 2013

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,

Joyce M. Whang

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

Indications for Use

510(k) Number (if known): K120922

Device Name: Guardian Dysphagia dual channel NMES unit

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 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Brian D. Pullin -S

Division of Neurological and
Physical Medicine Devices
510(k) Number: