K111985

DEC 3 0 2011

Section 5 - 510(k) Summary

For

Myoguide System

1. Submission Sponsor

Intronix Technologies Corporation
26 McEwan Drive
Suite 15
Bolton, Ontario L7E 1E6
CANADA
Phone: (905) 951.3361
Fax: (905) 951.3192
Contact: Joe Wojewoda, Production and Quality Manager

2. Submission Correspondent

Emergo Group
611 West 5th Street, Third Floor
Austin, TX 78701
Cell Phone: (508) 838.9139
Office Phone: (512) 327.9997
Fax: (512) 327.9998
Contact: Richard Vincins, Vice President, QA
Email: richard@emergogroup.com

3. Date Prepared

June 20th 2011

4. Device Name

Trade/Proprietary Name: Myoguide System
Common/Usual Name: Myoguide System Model 8008
Classification Name: Electrical Peripheral Nerve Stimulator
Classification Regulation: 868.2775
Classification Panel: Anesthesiology
Product Code: BXN, secondary GWL
Device Class: II

5. Predicate Devices

Medtronic A/S – Clavis EMG Device K062478
Xavant Technology – STIMPOD NMS450 K102084

6. Device Description

Myoguide is a battery powered, handheld, EMG amplifier with audio feedback, LCD EMG signal and device status display, and current stimulation ranging from 0 mA - 20 mA. This device is internally powered and rated for continuous use. The patient input connection is a type BF applied part. Myoguide will automatically power off after 30 minutes of inactivity to conserve battery life.

Myoguide is designed to amplify electrophysiological signals from muscle and provide audio feedback to assist clinicians in locating areas of muscle activity. The Stimulator can be used as an adjunct. Myoguide provides muscle and nerve localization information, to accurately guide and monitor needle electrode insertion, and/or injection of neuromodulator drugs, into a muscle in the human body. Any drug used will be that of the choice of the physician.

The large LCD display provides the complete system status at a glance. EMG audio, EMG signal display, EMG RMS Value, Integrated EMG signal strength and stimulation capability, increases efficacy for injection point localization. The simple control panel is intuitive and easy to operate.

Myoguide operates in two modes: "[EMG]" and "[Stimulation]". The default mode, "[EMG]", records electromyographic (EMG) signals from electrodes placed on the subject. The second mode, "[Stimulation]", enables Myoguide's onboard stimulator to stimulate through the needle electrode that was used to record the EMG. This enables the clinician to record and stimulate through the same needle electrode. The <Mode> switch is used to change the state of operation.

7. Intended Use

The Intronix Model 8008 Myoguide System (Myoguide) is a medical device intended as a stimulator for nerve localization as well as an aid for guidance of injections into the muscles.

8. Technological Characteristics and Substantial Equivalence

The following table compares the Myoguide System to the STIMPOD NMS450 and Clavis EMG predicate devices with respect to intended use, technological characteristics and principles of operation, providing more detailed information regarding the basis for the determination of substantial equivalence.

Comparison Table

Manufacturer	**Intronix Technologies Corporation**	**Xavant Technology**	**Medtronic A/S**	**Myoguide System Comparison to Predicate**
Trade Name	Myoguide System	STIMPOD NMS450	Clavis EMG Device	
510(k) Number	K111985	K102084	K062478	NA
Product Code	BXN, GWL	BXN	BXN, GWL	Same
Regulation Number	868.2775	868.2775	890.1375	The product code lists 868.2775 as the regulation number. The Intronix Myoguide System has the same intended use as the predicate device, the Medtronic Clavis EMG device.
Regulation Name	Electrical peripheral nerve stimulator	Electrical peripheral nerve stimulator	Diagnostic electromyograph	See note above for the regulation number
Indications for use:	The Intronix Model 8008 Myoguide System (Myoguide) is a medical device intended as a stimulator for nerve localization as well as an aid for guidance of injections into the muscles.	This product is a nerve stimulation device designed to be used by an anesthetist during 1. General Anaesthesia, for the purpose of establishing the efficacy of a Neuromuscular Blocking Agent using non-invasive surface electrodes (not supplied) 2. Regional Anaesthesia for the purpose of a. nerve mapping using the non-invasive Nerve Mapping Probe (supplied) and	CLAVIS is a medical device intended as a stimulator for nerve localization as well as an aid for guidance of injections into the muscle.	Same

Manufacturer	**Intronix Technologies Corporation**	**Xavant Technology**	**Medtronic A/S**	**Myoguide System Comparison to Predicate**
Trade Name	Myoguide System	STIMPOD NMS450	Clavis EMG Device	
		b. nerve locating using invasive electrodes/needles (not supplied).		
Overall Design	Myoguide is a ABS plastic enclosure, battery powered, handheld, EMG amplifier with audio feedback, LCD EMG signal and device status display; Myoguide operates in two modes: EMG and Stimulation	The STIMPOD NMS450 is a ABS plastic enclosure, battery powered, handheld, EMG amplifier with audio feedback, LCD EMG signal and device status display; STIMPOD NMS450 operates in four stimulation modes	Clavis EMG is a ABS plastic enclosure, battery powered, handheld, EMG amplifier with audio feedback, and LCD EMG signal; Clavis EMG operates in two modes: EMG and Stimulation	The three instruments are identical in technology aspects except the Myoguide and STIMPOD have an LCD display where the Clavis does not; this is not a significant difference as the Myoguide and STIMPOD displays the system status, stimulation settings, and EMG signal and utilizes audio indicators where the Clavis device only utilizes indicators lights and audio indicators
LCD Display	Yes; 160x64 resolution with or without backlight	Yes; with or without backlight	None	The Myoguide has an LCD display for complete device status and displays the EMG signal same as the STIMPOD; this is not a significant difference as the Myoguide displays the EMG signal and utilizes audio indicators where the Clavis device only utilizes indicators lights and audio indicators

Manufacturer	**Intronix Technologies Corporation**	**Xavant Technology**	**Medtronic A/S**	**Myoguide System Comparison to Predicate**
Trade Name	Myoguide System	STIMPOD NMS450	Clavis EMG Device	
Mode of Operation	Continuous operation	Continuous operation	Continuous operation	Same
Stimulation Wave	Square	Square	Square	Same
Stimulation Pulse Rate	1 Hz, 3 Hz, 5 Hz, 7 Hz, or 10 Hz	1 Hz, 2 Hz, 5 Hz, 50 Hz, or 100 Hz	1 Hz or 2 Hz	Same
Stimulation Pulse Width	50, 100, 200 or 500 µs	0.05, 0.1, 0.3, 0.5 or 1.0 ms	0.1 ms or 0.2 ms	Same
Stimulation Level	0 mA to 20 mA, steps by 1.0 mA	0 mA to 80 mA, steps by 0.2 mA	0 mA to 15 mA, steps by 1.0 mA	Same
Electrode Impedance	200Ω to 10kΩ	2000Ω to 0kΩ	200Ω to 7kΩ	Same
Complies with IEC 60601-1	Yes	Yes	Yes	Same
Complies with IEC 60601-1-2	Yes	Yes	Yes	Same
Complies with IEC 60601-2-40	Yes	Yes	Yes	Same
Power Supply	Internally powered, 4AA alkaline or rechargeable batteries	Internally powered, 4AA alkaline or rechargeable batteries	Internally powered, 9V alkaline or rechargeable battery	Same
Weight	225g (8 oz)	130g (4.6 oz)	185 g (6.5 oz)	Same
Dimensions (LxWxH)	150 x 100 x 54 mm (5.9" x 4.0" x 2.1")	145 x 90 x 30 mm (5.7" x 3.5" x 1.2")	140 x 80 x 20 mm	Same
Operating Conditions	+10°C to +40°C (+50°F to +104°F) 30 – 75% rH	+10°C to +40°C (+50°F to +104°F) 30 – 75% rH	+10°C to +40°C (+50°F to +104°F) 30 – 75% rH	Same
Input Cable	Three input (anode, anode, needle) with proprietary instrument connection port	Three input (anode, anode, needle) with proprietary instrument connection port	Three input (anode, anode, needle) with proprietary instrument connection port	Same

Manufacturer	**Intronix Technologies Corporation**	**Xavant Technology**	**Medtronic A/S**	**Myoguide System Comparison to Predicate**
Trade Name	Myoguide System	STIMPOD NMS450	Clavis EMG Device	
Input Cable Adapter	Single input adapter for standard touch-proof connection	Not available	Not available	N/A

9. Non-Clinical Testing

The device's hardware and software development, verification, and validation have been carried out in accordance with FDA guidelines. The software was tested against the established Software Design Specifications for each of the test plans to assure the device performs as intended. The Device Hazard analysis was completed and risk control implemented to reduce any identified hazards. The testing results supports that all the hardware specifications and software specifications have met the acceptance criteria for the device. The Myoguide System passed all testing and supports the claims of substantial equivalence and safe operation.

The Myoguide System complies with the applicable voluntary standards for Electromagnetic Compatibility and Safety. The device passed all the electrical and safety testing according to national and international standards.

10. Clinical Testing

There was no clinical testing required to support the medical device as the indications for use is equivalent to the predicate device. The substantial equivalence of the device is supported by the non-clinical testing. The verification and validation testing of the device software and electrical safety and EMC testing of the device was found to acceptable and supports the claims of substantial equivalence.

11. Conclusion

By definition, a device is substantially equivalent to a predicate device when the device has the same intended use and the same technological characteristics as the previously cleared predicate device. Or the device has the same intended use and different technological characteristics that can be demonstrated that the device is substantially equivalent to the predicate devices, and that the new device does not raise different questions regarding its safety and effectiveness as compared to the predicate devices.

It has been shown in this 510(k) submission that the difference between the Myoguide System and the predicate devices does not raise any questions regarding its safety and effectiveness. The Myoguide System, as designed and manufactured, is determined to be substantially equivalent to the referenced predicate devices.

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

DEC 3 0 2011

Intronix Technologies Corporation
C/O Mr. Richard Vincins, Vice President, Quality Affairs
Emergo Group
611 West 5th Street
Austin, Texas 78701

Re: K111985
Trade/Device Name: Myoguide System Model 8008
Regulation Number: 21 CFR 868.2775
Regulation Name: Electrical Peripheral Nerve Stimulator
Regulatory Class: II
Product Code: BXN
Dated: December 9, 2011
Received: December 13, 2011

Dear Mr. Vincins:

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,

for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section 4 - Indications for Use Statement

510(k) Number (if known): Not Assigned

Device Name: Myoguide System

Indications for Use:

The Intronix Model 8008 Myoguide System (Myoguide) is a medical device intended as a stimulator for nerve localization as well as an aid for guidance of injections into the muscles.

Prescription Use ___X____ (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 Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K111985