K102084

SECTION 4

DEC 16 2010

SECTION 4 – 510(k) SUMMARY

[As required by 21CFR807.92]

4.1 Date Prepared [21CFR807.92(a)(1)]

January 28, 2010

4.2 Submitter's Information [21CFR807.92(a)(1)]

Company Name:	XAVANT TECHNOLOGY (PTY) LTD
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Contact Person:	Brian Rothman
Contact Title:	Quality Assurance and Regulatory Compliance Officer
Contact Email:	brian@xavant.com

4.3 Trade Name, Common Name, Classification [21CFR807.92(a)(2)]

Trade Name:	STIMPOD NMS450 Nerve Stimulator
Common Name:	Battery Powered Peripheral Nerve Stimulator
Classification Name:	Battery Powered Nerve Stimulator per 21 CFR § 868.2775
Device Class:	Class II
Product Code:	BXN

SECTION 4

4.4 Identification of Predicate Device(s) [21CFR807.92(a)(3)]

PREDICATE DEVICES
HDC Corporation, NeuroTrace III (K023342) Xavant Technology, STIMPOD NMS400 (K093591) Life Technologies Inc, EzStim II (K954505)

There are no significant differences between the STIMPOD NMS450 Nerve Stimulator and the predicate devices that would adversely affect the use of the product. It is substantially equivalent to these devices in design, function, materials, operational principles and intended use.

4.5 Description of the Device [21CFR807.92(a)(4)]

The STIMPOD NMS450 is a battery powered peripheral nerve stimulators that can be used for

- nerve mapping using the non-invasive Nerve Mapping Probe (supplied)
- nerve locating using invasive electrodes/needles (not supplied)
- general anesthesia, for the purpose of establishing the efficacy of a Neuromuscular Blocking Agent using non-invasive surface electrodes (not supplied)

The stimulus is generated by a constant current source. The waveform is a square wave with various pulse width options.

The anode comprises of an ECG electrode (not supplied). The cathode comprises of

- a permanently attached nerve mapping probe (supplied) for nerve mapping,
- and/or a separate nerve locating needle (not supplied) for nerve locating,
- and/or another ECG electrode (not supplied) for NMBA monitoring, depending on the mode of the unit.

4.6 Intended Use [21CFR807.92(a)(5)]

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
   b. nerve locating using invasive electrodes/needles (not supplied)

SECTION 4

4.7 Technological Characteristics [21CFR807.92(a)(6)]

Stimulus Modes

Monophasic Square wave, repeating at 1Hz, 2Hz, 5Hz, 50Hz, 100Hz

Stimulation patterns: Train-of-Four, Double Burst, Post-Tetanic-Count, Twitch, Tetanus

Current Ranges

Nerve mapping:0 – 20mA

Pulse Width: 0.05ms, 0.1ms, 0.3ms, 0.5ms, 1ms

Nerve Locating:0.0 – 5.0mA

Pulse Width: 0.05ms, 0.1ms, 0.3ms, 0.5ms, 1ms

NMBA Mode: 0.0 – 80.0mA

Pulse Width: 0.2ms

Stimulation Voltages

Nerve Mapping: Max 400V p-p

Nerve Locating:Max 100V p-p

NMBA Mode: Max 400V p-p

Waveform

Constant Current

Monophasic

Squarewave

Nerve Mapping Probe

Nerve Mapping Probe designed for non-invasive nerve mapping

Three-Dimensional Accelerometer

Three-dimensional accelerometer designed to provide feedback for NMBA monitoring

Technical Specifications

SECTION 4

Power Supply	4 x AAA Alkaline Batteries
Weight	130g
Dimensions	145mm x 90mm x 30mm

The STIMPOD NMS450 Peripheral Nerve Stimulator is equivalent to the identified predicates in technical properties, design and utilized materials of construction of the currently marketed predicate devices.

4.8 Product Similarities with the predicates

The similarities between the subject device and cited predicate nerve stimulator product are summarized below:

System components	Equivalent
Indications for Use	Equivalent
Principles of Operation	Equivalent
Required Labeling	Equivalent
Contraindications	Equivalent
Materials	Equivalent
Electrical Performance	Equivalent

The STIMPOD NMS450 has the similar technological characteristics as the predicate device, device design, appearance, materials and indication for use.

The STIMPOD NMS450 has the similar technical properties as the predicate device; waveform and current settings, pulse width setting, current settings in NMBA.
The STIMPOD NMS450 has been subjected to extensive safety, performance and product validations prior to release. Safety testing including biocompatibility test has been performed to ensure that the devices comply with the applicable international and US regulations.

4.9 Conclusion

Clinical Use

Each of the above devices:

- used for the same clinical condition or purpose;
- have similar relevant critical performance according to expected clinical effect for specific intended use.

Technical Characteristics

Each of the above devices:

- used under similar conditions of use;
- have similar specifications and properties;
- are of similar design;

- use similar deployment methods;
- have similar principles of operation; and
- have similar electrical performance.

Biological Characteristics

Each of the above devices has:

- no known biocompatibility issues; and
- no known effect on the environment, or to other devices.

Based upon the above clinical use, technical and biological considerations the manufacturer believes that the STIMPOD NMS450 Peripheral Nerve Stimulators are substantially equivalent to the identified predicate devices, and does not raise any new questions of safety and effectiveness.

Xavant Technology, will update and include in this summary any other information deemed reasonably necessary by the FDA.

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

Xavant Technology (PTY) Limited
C/O Mr. Marc M. Mouser
Responsible Third Part Official
Underwriters Laboratories, Incorporated
2600 NW Lake Road
Camas, Washington 98607-9526

DEC 16 2010

Re: K102084
Trade/Device Name: STIMPOD NMS450 Nerve Stimulator
Regulation Number: 21 CFR 868.2775
Regulation Name: Electrical Peripheral Nerve Stimulator
Regulatory Class: II
Product Code: BXN
Dated: November 29, 2010
Received: December 2, 2010

Dear Mr. Mouser:

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,

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

INDICATIONS FOR USE

K102084

510(k) Number (if known):

DEC 16 2010

Device Name: **STIMPOD NMS450 Nerve Stimulator**

Indications for Use:

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).
   b. Nerve locating using invasive electrodes/needles (not supplied).

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)

L Schultz

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K102084