ATTACHMENT 4

K110118

510(k) SUMMARY

FEB 17 2011

[As required by 21CFR807.92]

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

January 10, 2011

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

Company Name:	XAVANT Technology (Pty) LTD
Street Address:	Ravello, 1st Floor. Delmondo Office Park 169 Garstfontein Road Ashlea Gardens
City:	Pretoria
State/Province:	Gauteng
Country:	South Africa
Telephone:	+27(0) 12 755 9491
Facsimile:	+27(0) 12 346 7271
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:	Stimtrode 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

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

PREDICATE DEVICES
Xavant Technology, XPOD/XMAP Nerve Stimulator (K072092)

There are no significant differences between the Stimtrode Nerve Stimulator and the predicate devices which 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 Stimtrode device is a battery powered peripheral nerve stimulators that can be used for

- nerve locating using invasive electrodes/needles (not supplied)

The stimulus is generated by a constant current source. The waveform is a square wave with 3 options for pulse width. These are: 0.1, 0.3 and 0.5 milliseconds.

The units will continuously check for a closed circuit at 2Hz. Once a closed circuit is detected, the twitches will repeat at 2Hz, until an open circuit is detected.

The unit is permanently attached to the anode. The anode comprises a modified ECG type pad. The cathode comprises of a nerve locating needle that is attached at time of use.

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

The Stimtrode™ is intended to be used by an anesthetist during a peripheral nerve block procedure for nerve localization using invasive electrodes/needles (supplied separately).

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

Stimulus Modes

Monophasic square wave, repeating at 2Hz

Current Ranges

Current	0.0 – 1.6mA adjustable in 0.1mA increments
	1.6 – 5.0mA adjustable in 0.2mA increments
Pulse Width:	0.1ms, 0.3ms, 0.5ms

Stimulation Voltages

Max 100V p-p

Waveform

Constant Current

Monophasic

Squarewave

Technical Specifications

Power Supply	2x 3V internal, non-rechargable $LiMnO_2$ Batteries (CR1220)
Weight	36g
Dimensions	75mm x 75mm x 20mm

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

Mr. Brian Rothman
Quality Assurance and Regulatory Compliance Officer
XAVANT Technology (Pty) Limited
Ravello, 1st Floor, Delmondo Office Park
169 Garstfontein Road
Ashlea Gardens
Pretoria, Gauteng
South Africa

FEB 17 2011

Re: K110118
Trade/Device Name: Stimtrode Nerve Stimulator
Regulation Number: 21 CFR 868.2775
Regulation Name: Electrical Peripheral Nerve Stimulator
Regulatory Class: II
Product Code: BXN
Dated: January 10, 2011
Received: January 18, 2011

Dear Mr. Rothman:

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

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

ATTACHEMENT 2

INDICATIONS FOR USE

510(k) Number (if known):

Device Name: **Stimtrode nerve stimulator**

Indications for Use:

The Stimtrode is intended to be used by an anesthetist during a peripheral nerve block procedure for nerve localization using invasive electrodes/needles (supplied separately).

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

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