SECTION 4

K072092

SECTION 4 – 510(k) SUMMARY

NOV 15 2007

[As required by 21CFR807.92]

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

July 26, 2007

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

Company Name:	XAVANT Technology (Pty) LTD
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Telephone:	+27(0) 12 329 1188
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Contact Person:	Roché van Rensburg
Contact Title:	Director
Contact Email:	roche@xavant.com

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

Trade Name:	The XPOD/XMAP 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

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

PREDICATE DEVICES
HDC CORP, Neuro-Trace III (K023342) Stockert GmbH, Stimuplex HNS12 (K052313)

There are no significant differences between the XPOD/XMAP 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 XPod/XMap devices are 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)

The stimulus is generated by a constant current source. The waveform is a square wave with 2 options for pulse width. These are: 0.1 and 0.3 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.

Visual feedback of the current amplitude as well as pulse-width is given by means of an LCD screen.

The unit is permanently attached to the anode. The anode comprises a modified ECG type pad. The cathode comprises a permanently attached nerve mapping probe, in the XMap model, and a separate nerve locating needle in the XPod model.

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

The XPOD/XMAP is a nerve stimulation device intended to be used by an anesthetist during regional anesthesia procedures wherever peripheral anesthesia is normally applied. The XMAP is intended for percutaneous nerve mapping using the non-invasive Nerve Mapping Probe (supplied). The XPOD is intended for nerve localization using invasive electrodes/needles (not supplied).

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

Stimulus Modes

Square wave, repeating at 2Hz

Current Ranges

Xmap:	0 – 20mA adjustable in 1mA increments
Pulse Width:	0.1ms, 0.3ms
Xpod:	0.0 – 1.6mA adjustable in 0.1mA increments
	1.6 – 5.0mA adjustable in 0.2mA increments
Pulse Width:	0.1ms, 0.3ms

Stimulation Voltages

XMap:	Max 100V p-p
XPod:	Max 100V p-p

Waveform

Constant Current

Monophasic

Squarewave

Nerve Mapping Probe

Ergonomically designed cutaneous Nerve Mapping Probe

Technical Specifications

Power Supply	2x 1.5V AAAA Alkaline Batteries
Weight	60g
Dimensions	80mm x 80mm x 22mm

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 1 5 2007

Mr. Roche Van Rensburg
Director
Xavant Technology Party, Limited
181 Soutpansberg Road, Rietondale
Pretoria, Gauteng 0084
South Africa

Re: K072092
Trade/Device Name: XPOD/XMAP Nerve Stimulator
Regulation Number: 868.2775
Regulation Name: Electrical Peripheral Nerve Stimulator
Regulatory Class: II
Product Code: BXN
Dated: October 5, 2007
Received: October 29, 2007

Dear Mr. Rensburg:

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 (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D.
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

510(k) Number (if known):

Device Name: The XPOD/XMAP Nerve Stimulator

Indications for Use:

The XPOD/XMAP is a nerve stimulation device intended to be used by an anesthetist during regional anesthesia procedures wherever peripheral anesthesia is normally applied. The XMAP is intended for percutaneous nerve mapping using the non-invasive Nerve Mapping Probe (supplied). The XPOD is intended for nerve localization 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)

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

510(k) Number: K022092