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

January 18, 2017

Xavant Technology (PTY) Ltd
Roche Janse van Rensberg
Chairman
Unit 102 The Tannery Industrial Park
309 Derdepoort Road
Silverton, ZA 0184 Gauteng

Re: K161091
Trade/Device Name: STIMPOD NMS460 Nerve Stimulator
Regulation Number: 21 CFR 882.5890
Regulation Name: Transcutaneous Electrical Nerve Stimulator For Pain Relief
Regulatory Class: Class II
Product Code: GZJ
Dated: December 2, 2016
Received: December 2, 2016

Dear Roche van Rensberg:

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 contact the Division of Industry and Consumer Education 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. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 Industry and Consumer Education 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,

William J. Heetderks -A

Digitally signed by William J. Heetderks -A
DN: c=US, o=U.S. Government, ou=HHS, ou=NIH, ou=People, 0.9.2342.19200300.100.1.1=0010149848, cn=William J. Heetderks -A
Date: 2017.01.18 16:51:40 -05'00'

for Carlos L. Peña, PhD, MS
Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K161091

Device Name
STIMPOD NMS460 Nerve Stimulator

Indications for Use *(Describe)*
The STIMPOD NMS460 Nerve Stimulator is a Transcutaneous Electrical Nerve Stimulation (TENS) device used for symptomatic relief and management of chronic intractable pain and/or as an adjunctive treatment in the management of post-surgical pain, post traumatic acute pain problems, as well as an adjunct for pain control due to rehabilitation.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

This 501(k) summary is prepared in accordance with the requirements of
21 CFR 807.92
K161091

Date this Summary was Prepared [21CFR807.92(a)(1)]

Date Prepared: February 2016

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

Company Name:	XAVANT TECHNOLOGY (PTY) LTD
Street Address:	Unit 102 The Tannery Industrial Park 309 Derdepoort Road Silverton
City:	Pretoria
State/Province:	Gauteng
Country:	South Africa
Telephone:	+27(0) 12 743 5959
Facsimile:	+27(0) 86 547 0026
Contact Person:	R. Janse van Rensburg
Contact Title:	Chairman
Contact Email:	roche@xavant.com

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

Trade Name: STIMPOD NMS460 Nerve Stimulator
Common Name: TENS (Transcutaneous Electronic Nerve Stimulator) device
Device Class: Class II
Product Code: GZJ (Stimulator, nerve, transcutaneous)

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

PREDICATE DEVICES
The STIMPOD NMS460 Nerve Stimulator is similar to the following predicate device as a TENS device under classification GZJ: Acticare (K081835), Bioinduction Ltd The STIMPOD NMS460 Nerve Stimulator mapping probe is similar to the following predicate device under classification BXN: STIMPOD NMS400 (K093591), Xavant Technology

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

The STIMPOD NMS460 Nerve Stimulator is a hand held low frequency neuromodulation Transcutaneous Electrical Nerve Stimulation (TENS) device, used for symptomatic relief and management of chronic intractable pain and/or as an adjunctive treatment in the management of post-surgical pain, post traumatic acute pain, as well as an adjunct for pain control due to rehabilitation exercises.

The STIMPOD NMS460 Nerve Stimulator offers two types of waveforms for the management of pain. The first is a Monophasic Square Wave, which is typical of normal TENS machines. The second waveform is a Hybrid RF waveform which consists of a Monophasic Square Wave with a superimposed Radio Frequency waveform. This waveform is proprietary and is unique to STIMPOD NMS460 Nerve Stimulator.

Indications for Use and Substantial Equivalence [21 CFR807.92(a)(5)]

Parameters	**STIMPOD NMS460 Nerve Stimulator (Subject device)**	**Acticare (Predicate device) K081835**
Indications for Use	The STIMPOD NMS460 Nerve Stimulator is a low frequency neuromodulation Transcutaneous Electrical Nerve Stimulation device, used for symptomatic relief and management of chronic intractable pain and/or as an adjunctive treatment in the management of post-surgical pain, post traumatic acute pain, as well as and adjunct for pain control due to rehabilitation exercises	As a transcutaneous electronic nerve stimulation(tens) device for: the symptomatic relief of chronic intractable pain, and as an adjunctive treatment in the management of post-surgical or post traumatic pain. As a neuromuscular electrostimulation (nmes) device for: the relaxation of muscle spasm, prevention of retardation of disuse atrophy, increasing local blood circulation, muscle re-education, immediate post-surgical stimulation of the calf muscles to prevent venous thrombosis and to maintain or increase the range of motion.
Number of Output Modes	1	5 (Normal, Powerful, Long Pulse, Burst Mode 1 and 2)
Number of Waveforms	2 (Monophasic, Biphasic with offset)	3 (Monophasic, Biphasic, Twin Peak)
Number of Output Channels	1	1
Method of Channel Isolation	N/A	N/A
Current/Voltage Source	Current source	Voltage source
Automatic Overload	Yes	N/A

Detection		
Automatic No-Load Detection	Yes	Yes
Automatic Shut Off	Yes	
User Override Control	Yes	Yes
Housing Materials and Construction	ABS Plastic	ABS Plastic
Current Range	0-30mA	20mA
Pulse width options	0.1ms, 0.2ms	0.005ms to 0.1ms
Maximum stimulation voltage	220V	250V
Maximum output current	43.7mA	127mA
Net charge	6.06µC	14.88µC
Maximum Current Density	93.28µA/mm^2 @500Ohm	232.62µA/mm^2 @500Ohm
Maximum Average Power Density	71.5µW/mm^2 @500Ohm	378.575µW/mm^2 @500Ohm
Waveform	Monophasic square wave/Hybrid RF wave	Biphasic, Monophasic, Twin Peak
Stimulation Frequency	1Hz, 2Hz, 5Hz, 10Hz +5%	1Hz to 500kHz
Load Impedance	7kOhm	12.5kOhm
Treatment Timer Maximum	99 minutes	180 minutes
Device Classification	Class IIa, Type BF	Class IIa, Type BF
Power Supply	4 x AAA alkaline batteries	4 x AA alkaline batteries

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

The STIMPPOD NMS460 Nerve Stimulator is very similar to the predicate device and has technology characteristics that are substantially equivalent to the predicate device.

The STIMPOD NMS460 and the Acticare predicate device transmit electrical pulses through the skin. The range of amplitudes, pulse widths, frequencies and polarities delivered by the STIMPOD NMS460 Nerve Stimulator is within the ranges delivered by the predicate device.

The STIMPOD NMS460 Nerve Stimulator and the predicate device can be used in clinical environments.

Summary of detailed comparison between the Stimpod NMS460 and Acticare devices for the listed worst-case scenarios:

Device	Calculation/Result	Mode	Load/s
Maximum output Voltage			
NMS460	228V	Monophasic Square Wave	10 kOhm
Acticare	62.4V	Monophasic Square Wave	5 kOhm
Maximum output Current			
NMS460	43.7mA (Peak)	Hybrid RF Mode	500 Ohm
Acticare	127mA (Peak)	Monophasic Square Wave	500 Ohm
Maximum Average Current (Over primary phase)			
NMS460	29.85mA	Monophasic Square Wave	500 Ohm

Acticare	74.44mA	Monophasic Square Wave	500 Ohm
Duration of primary phase			
NMS460	206us	Hybrid RF Mode	10 kOhm
Acticare	200.4us	Monophasic Square Wave	5 kOhm
Pulse Duration			
NMS460	206us	Hybrid RF Mode	10 kOhm
Acticare	200.4us	Monophasic Square Wave	5 kOhm
Net Charge			
NMS460	6.06 uC	Hybrid RF Mode	500 Ohm
Acticare	14.88 uC	Monophasic Square Wave	500 Ohm
Maximum Average Phase Charge			
NMS460	6.06 uC	Hybrid RF Mode	500 Ohm
Acticare	14.88 uC	Monophasic Square Wave	500 Ohm
Maximum Current Density			
NMS460	$93.281 \times 10^{-6} \frac{A}{mm^2}$	Hybrid RF Mode	500 Ohm
Acticare	$232.619 \times 10^{-6} \frac{A}{mm^2}$	Monophasic Square Wave	500 Ohm
Maximum Average Power Density			
NMS460	$591.783 \times 10^{-6} \frac{W}{mm^2}$	Hybrid RF Mode	5 kOhm
Acticare	$378.575 \times 10^{-6} \frac{W}{mm^2}$	Monophasic Square Wave	500 Ohm

As indicated above the Acticare can deliver up to three times as much peak current and more than twice the average phase current compared to the NMS460. For the selected pulse width of 200us, both units performed within 5% of the pulse width setting. With regards to the net charge and maximum average phase charge and maximum current density, the Acticare again has significantly higher values than the Stimpod NMS460 Nerve Stimulator.

Considering these factors, it is reasonable to conclude that the Stimpod NMS460 Nerve Stimulator is substantially equivalent regarding safety to the Acticare.

Comparison of RF component of Hybrid RF Waveform of Stimpod NMS460 Nerve Stimulator with Burst Modes in the RF range of the Acticare:

RF Stimulating Options		
	Articare TSE (refer to Appendix B for detail)	Stimpod NMS460 Nerve Stimulator
Waveform Options	Biphasic, Monophasic, Twin Peak	Biphasic, with a DC offset, decaying
Pulse Width Options	10µs – 2s	100µs, 200µs
Pulse Repetition Rate Options	0.25Hz – 2kHz	1,2,5,10 Hz
RF Frequency Options	5kHz – 500kHz	160kHz fixed

As indicated above the RF parameters offered by the Stimpod NMS460 Nerve Stimulator are well within the range of RF parameters offered by the Articare TSE as far as frequency of stimulation, pulse widths, pulse repetition rates and current amplitude are concerned.

Based on the fact that the Stimpod NMS450 Nerve Stimulator is designed as a current source and delivers according to its specification for loads up to 5 kOhm, it is reasonable to conclude that the NMS460 is substantially equivalent to the Acticare regarding effectiveness.

Contra-indications

Known neurological disorders.

Biocompatibility

Materials used in the manufacture of the STIMPOD NMS460 Nerve Stimulator are safe and pose no threat or danger if they come into contact with human skin. Both the stainless steel (316L) used in the construction of the probe and the ABS plastic used in the manufacture of the enclosure have previously been used in the manufacture of medical and surgical instruments. The materials, referring to the stainless steel and ABS plastic, have also been previously used in FDA approved medical devices (K093591).

The material used and the physical properties of the materials that come into contact with the patient are equivalent with the comparative devices and pose no danger to the patient.

Software level of concern

Software level of concern: Moderate

Non-clinical Testing [21CFR807.92(b)(1)]

Electrical Safety

The STIMPOD NMS460 Nerve Stimulator was tested for patient safety in accordance with the following standards:
IEC 60601-1: 2005, Medical electrical equipment – Part 1: General requirements for basic safety and essential performance.
Test results indicated that the STIMPOD NMS460 Nerve Stimulator complies with the applicable Standards.

Electromagnetic Compatibility

The STIMPOD NMS460 Nerve Stimulator was tested for EMC in accordance with the following standard:
IEC 60601-1-2: 2007, Medical Electrical Equipment, Part 1: Part 1-2: General Requirements for Safety – Collateral Standard: Electromagnetic Compatibility-Requirements and Tests.
Test results indicated that the STIMPOD NMS460 Nerve Stimulator complies with the applicable Standard.

Safety of Nerve and Muscle Stimulators

The STIMPOD NMS460 Nerve Stimulator was tested for the requirements for safety of nerve and muscle stimulators:
IEC 60601-2-10: 2015, Particular requirements for the basic safety and essential performance of nerve and muscle stimulators.
Test results indicated that the STIMPOD NMS460 Nerve Stimulator complies with the applicable Standard.

Conclusion [21CFR807.92(b)(3)]

The STIMPOD NMS460 and the Acticare predicate device have the same intended use and similar technical characteristics, performances and applications. The information supplied in the full 510(k) application illustrates that the device does not pose any new question of safety or effectiveness. STIMPOD NMS460 is substantially equivalent to the predicate device.