October 16, 2022

Xavant Technology (Pty) Ltd
Roche Van Rensburg
Chief Executive Officer
Unit 102 Tannery Industrial Park, 309 Derdepoort Road
Silverton
Pretoria, Gauteng 0184
South Africa

Re: K213049
Trade/Device Name: STIMPOD NMS450 Nerve Stimulator
Regulation Number: 21 CFR 868.2775
Regulation Name: Electrical Peripheral Nerve Stimulator
Regulatory Class: Class II
Product Code: BXN
Dated: September 1, 2022
Received: September 12, 2022

Dear Roche Van 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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

James J. Lee, Ph.D.
Division Director
DHT1C: Division of Sleep Disordered Breathing, Respiratory and Anesthsia Devices
OHT1: Office of Ophthalmic, Anesthesia, Respiratory, ENT and Dental Devices
Office of Product Evaluation and Quality
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K213049

Device Name
STIMPOD NMS450 Nerve Stimulator

Indications for Use *(Describe)*

This device is a nerve stimulation device designed to be used by an anesthetist during:
1. General anesthesia, for the purpose of establishing the efficacy of a Neuromuscular Blocking Agent using non-invasive surface electrodes.
2. Regional anesthesia, for the purpose of:
i. nerve mapping using the non-invasive Nerve Mapping Probe (supplied)
ii. nerve locating using invasive needles (not supplied)

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.

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This 510(k) Summary was prepared in accordance with the requirements of 21CFR807.92

5.1 Date Prepared

08 September, 2022

5.2 Submitter's Information

Company Name:	XAVANT TECHNOLOGY (PTY) LTD
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Contact Person:	Roche Janse van Rensburg
Contact Title:	Chief Executive Officer
Contact Email:	compliance@xavant.com

5.3 Trade Name, Common Name, Classification

Type of 510(k) submission	Traditional
Trade Name:	STIMPOD NMS450 Nerve Stimulator
Common Name:	Battery Powered Peripheral Nerve Stimulator
Classification Name:	Battery Powered Nerve Stimulator per 21 CFR § 868.2775
Regulatory Class:	Class II
Product Code:	BXN
Panel:	Anesthesiology
Reason for Submission	New Accessory

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5.4 Identification of Predicate/Reference Device(s)

PREDICATE DEVICE
Xavant Technology, STIMPOD NMS450 (K102084) This predicate device has not been subject to a design-related recall.
REFERENCE DEVICE
Senzime, Tetragraph (K190795) This reference device has not been subject to a design-related recall.

5.5 Description of the Device

The STIMPOD NMS450 is a quantitative Neuromuscular Transmission (NMT) Monitor which provides real-time quantitative feedback utilizing tri-axial accelerometery.

The STIMPOD NMS450 is also a precision nerve locating tool used for localizing specific neural pathways. Localization of nerves by electrical stimulation involves connecting the nerve stimulator to a conducting needle through which local anaesthetics can be injected. The distance of the needle (cathode) from the nerve can be estimated by establishing the minimum threshold current required, to facilitate a neuromuscular response.

The STIMPOD NMS450 currently makes use of 3 dimensional acceleromyography (AMG) as the measurement technology of choice for objective Neuromuscular Transmission (NMT) monitoring in surgery. Although AMG is still the de-facto standard in industry, the use of electromyography (EMG) has gained renewed interest in NMT monitoring applications where the introduction of robotic surgeries, new surgical techniques, and changes in workflow, for instance, made the use of AMG impracticable.

In order to address this steadily increasing market demand for EMG sensor technology in NMT monitoring applications, Xavant identified the need to design and develop a dedicated NMT Monitoring Cable (EMG) that could be used interchangeably with the existing NMT Monitoring Cable (AMG) already in use with the STIMPOD NMS450.

The NMT Monitoring Cable (EMG) was specifically designed for use with the STIMPOD NMS450 to assist anaesthesiologists in theatre with monitoring the efficacy of Neuromuscular Blocking Agents (NMBAs).

The NMT Monitoring Cable (EMG) was designed with an intelligent EMG signal processing module (henceforth referred to as the µEMG) on one end of the cable for connection to an EMG electrode, and with a standard FireWire connector on the other end for connection to the STIMPOD NMS450.

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The µEMG makes provision for the following interfaces:

1. a wireline communications interface to exchange information with the STIMPOD NMS450,
2. an electrical interface to condition and sample the EMG signals picked up by the measurement contact points of an attached EMG electrode array,
3. an electrical interface to (i) detect the stimulation signals generated by the STIMPOD NMS450, and (ii) route them to the stimulation contact points of an attached EMG electrode array,
4. a visual interface to indicate the state (powered, connected etc.) of the device.

5.6 Substantial Equivalence Discussion

The following device comparisons are made:

1. The STIMPOD NMS450 to the predicate device STIMPOD NMS450. STIMPOD NMS450's 510(k) clearance (K102084) means it is legally marketed;
2. The STIMPOD NMS450 to the reference device Tetragraph Neuromuscular Transmission Monitor from Senzime AB. Tetragraph's 510(k) clearance (K190795) means it is legally marketed.

Intended Use

FDA product Code of the predicate device and that of the subject device is given as "BXN" while that of the reference device is given as "KOI" – both products codes, however, are assigned under Regulation No. 21 CFR 868.2775 which applies to "Electrical Peripheral Nerve Stimulators" with the following intended use:

"An electrical peripheral nerve stimulator (neuromuscular blockade monitor) is a device used to apply an electrical current to a patient to test the level of pharmacological effect of anesthetic drugs and gases".

Indications for Use

This device is a nerve stimulation device designed to be used by an anaesthetist during:

1. General anaesthesia, for the purpose of establishing the efficacy of a Neuromuscular Blocking Agent using non-invasive surface electrodes.
2. Regional anaesthesia, for the purpose of:
   i. Nerve mapping using the non-invasive Nerve Mapping Probe (supplied)
   ii. Nerve locating using invasive needles (not supplied).

The subject and predicate devices have identical Indications for Use. The subject and reference devices are compared with respect to their mutual indications only. Both the devices are indicted for monitoring the efficacy (which can be defined as "the relaxation of the patient" as indicated in the reference device Indications for Use statement) of a Neuromuscular Blocking Agent.

Intended User and Patient Population

The intended user for both the subject device and predicate device is identical:

- The subject device and predicate device are both indicated for use by medical professionals with knowledge of anatomy

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The patient population for both the subject device and predicate device is similar:

- The reference device is for use with patients (excluding neonates). For the subject device, the patient population includes patients of all ages, weight, and nationality (excluding neonates for electromyography).

Substantial Equivalence Table

To demonstrate substantial equivalence with respect to intended use, technological characteristics, and principles of operation, two tables of Comparison of Characteristics are presented. The first table shows a comparison between the STIMPOD NMS450 (subject device) and the predicate device. The second table shows a comparison between the STIMPOD NMS450 (subject) device and the reference device for those characteristics where the subject device and predicate device had differences. The tables are accompanied by a discussion of all similarities and differences between the devices and therefore provide sufficient detailed information regarding the basis for the determination of substantial equivalence.

Comparison between Subject Device and Predicate Device

Characteristic	Subject Device	Predicate Device	Discussion
Trade Name	STIMPOD NMS450	STIMPOD NMS450	Identical
Product Code	BXN	BXN	Identical
Device Class	Class II	Class II	Identical
Classification Name	Electrical Peripheral Nerve Stimulator	Electrical Peripheral Nerve Stimulator	Identical
Regulation No.	886.2775	886.2775	Identical
Classification Panel	Anaesthesiology	Anaesthesiology	Identical
Intended Use	An electrical peripheral nerve stimulator (neuromuscular blockade monitor) used to apply an electrical current to a patient to test the level of pharmacological effect of anesthetic drugs and gases	An electrical peripheral nerve stimulator (neuromuscular blockade monitor) used to apply an electrical current to a patient to test the level of pharmacological effect of anesthetic drugs and gases	Identical
Indication for Use	This device is a nerve stimulation device designed to be used by an anaesthetist during: 1. general anesthesia, for the purpose of establishing the efficacy of a Neuromuscular Blocking Agent using non-invasive surface electrodes.	This device is a nerve stimulation device designed to be used by an anaesthetist during: 1. general anesthesia, for the purpose of establishing the efficacy of a Neuromuscular Blocking Agent using non-invasive surface electrodes.	Identical

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Characteristic	Subject Device	Predicate Device	Discussion
	2. regional anesthesia, for the purpose of: i. nerve mapping using the non-invasive Nerve Mapping Probe (supplied) ii. nerve locating using invasive needles (not supplied)	2. regional anesthesia, for the purpose of: - nerve mapping using the non-invasive Nerve Mapping Probe (supplied) - nerve locating using invasive needles (not supplied)	Identical
Device Components	**1. Nerve Stimulator/s** i. STIMPOD NMS450	**1. Nerve Stimulator/s** i. STIMPOD NMS450	Identical
	2. Patient Cable/s i. NMT Monitoring Cable (AMG) ii. Nerve Locating Cable iii. Nerve Mapping/Locating Cable	**2. Patient Cable/s** i. NMT Monitoring Cable (AMG) ii. Nerve Locating Cable iii. Nerve Mapping/Locating Cable	Identical
	3. Applied Part/s i. AMG Sensor	**3. Applied Part/s** i. AMG Sensor	Identical
	4. Power Cable/s None.	**4. Power Cable/s** None.	Identical
Waveform	Monophasic, constant current, square pulse	Monophasic, constant current, square pulse	Identical
Pulse Width	200µS	200µS	Identical
Stimulation Patterns	**Waveform:** Monophasic, constant current, square pulse with a fixed pulse width of 200ms **Pulse Repetition Frequency:** i. **TOF:** 4 pulses at 2Hz ii. **TWI(Twitch):** 1Hz, 2Hz, 5Hz iii. **Tetanic Stimulus:** 50Hz or 100Hz iv. **PTC Stimulation:** 50Hz Tetanic stimulus for 5 seconds, followed by 20 TWI pulses at 1Hz	**Waveform:** Monophasic, constant current, square pulse with a fixed pulse width of 200ms **Pulse Repetition Frequency:** i. **TOF:** 4 pulses at 2Hz ii. **TWI(Twitch):** 1Hz, 2Hz, 5Hz iii. **Tetanic Stimulus:** 50Hz or 100Hz iv. **PTC Stimulation:** 50Hz Tetanic stimulus for 5 seconds, followed by 20 TWI pulses at 1Hz	Identical
Current Characteristics	**Electrode/Skin Resistance:** 0-5000 ohm maximum **Current:** 5-80mA peak **Voltage:** 0 - 400V peak, depending on skin impedance	**Electrode/Skin Resistance:** 0-5000 ohm maximum **Current:** 5-80mA peak **Voltage:** 0 - 400V peak, depending on skin impedance	Identical
Control Mechanism	Digitally controlled by a microprocessor	Digitally controlled by a microprocessor	Identical

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Characteristic	Subject Device	Predicate Device	Discussion
Energy Type	**Battery:** 4 X AAA alkaline batteries, 6V, 1.2Ah **Charger:** None.	**Battery:** 4 X AAA alkaline batteries, 6V, 1.2Ah **Charger:** None.	Identical
NMT Monitoring Cable (AMG)	**Type:** Reusable **Communications:** STIMPOD proprietary. **Attachment:** Integral friction strap.	**Type:** Reusable **Communications:** STIMPOD proprietary. **Attachment:** Integral friction strap.	Identical
NMT Monitoring Cable (EMG)	**Type:** Reusable **Communications:** STIMPOD proprietary. **EMG Electrode Connector:** Proprietary frictional & magnetic Retention mechanism.	Not applicable	The predicate device does not include the NMT Monitoring Cable (EMG) as this is a new addition. Comparison provided with reference device.
EMG Electrode	**Type:** Self-adhesive, Single Use **Evoked Response Monitoring:** Electromyography. **Form Factor:** 2 Stimulation contact pads and 2 recording contact pads. **Ambidexterity:** Usable on left and right hand. **Application Site:** Distal stimulation of the Ulnar Nerve with CMAP recording of the Adductor Pollicis muscle.	Not applicable	The predicate device does not include the EMG Electrode as this is a new addition. Comparison provided with reference device.

Comparison between Subject Device and Reference Device

Characteristic	Subject Device	Reference Device	Discussion
Trade Name	STIMPOD NMS450	Tetragraph	Trade names are different.
Product Code	BXN	KOI	Similar. No new questions of safety and effectiveness raised.
Device Class	Class II	Class II	Identical
Classification Name	Electrical Peripheral Nerve Stimulator	Electrical Peripheral Nerve Stimulator	Identical

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Characteristic	Subject Device	Reference Device	Discussion
Regulation No.	886.2775	868.2775	Identical
Classification Panel	Anaesthesiology	Anesthesiology	Identical
Device Components	**1. Patient Cable/s** i. NMT Monitoring Cable (EMG)	**1. Patient Cable/s** i. TetraCord EMG Patient Cable	Similar. No new questions of safety and effectiveness raised.
	2. Applied Part/s EMG Electrode	**2. Applied Part/s** i. TetraSense EMG Electrode	Similar. No new questions of safety and effectiveness raised.
NMT Monitoring Cable (EMG)	**Type:** Reusable **Communications:** STIMPOD proprietary. **EMG Electrode Connector:** Proprietary frictional & magnetic Retention mechanism.	**Type:** Reusable **Communications:** TetraGraph proprietary **EMG Electrode Connector:** Proprietary frictional Retention mechanism.	Both cables are reusable. See discussion of differences below.
EMG Electrode	**Type:** Self-adhesive, Single Use **Evoked Response Monitoring:** Electromyography. **Form Factor:** 2 Stimulation contact pads and 2 recording contact pads. **Ambidexterity:** Usable on left and right hand. **Application Site:** Distal stimulation of the Ulnar Nerve with CMAP recording of the Adductor Pollicis muscle.	**Type:** Self Adhesive, Single Use **Evoked Response Monitoring:** Electromyography **Form Factor:** 2 Stimulation contact pads and 2 recording contact pads. **Ambidexterity:** Usable on left and right hand. **Application Site:** Distal stimulation of the Ulnar Nerve with CMAP recording of the Adductor Pollicis muscle.	The type, measuring technology, form factor and application site are identical. See discussion of differences below.

Discussion of differences:

NMT Monitoring

1. The specific means of communication that is used by the subject device to transfer measured EMG data from the electrode can be achieved in multiple different ways, and therefor does not need to be the same as that being used by the reference device.
2. The materials and construction of the NMT Monitoring Cable (EMG) used for the subject device differs from that of the EMG cable used for the reference device. As above, the patient cable for the two devices can be built from multiple different materials and

constructed in multiple different ways, and therefore do not need to be the same to achieve the same intended purpose.
3. The retention mechanism used in the construction of the patient cables for both devices is different, but the retention force offered by the connector used for the subject device is better or larger than that of the connector used for the reference device.

EMG Electrode

4. The materials used in the construction of the EMG electrodes of the two devices are different, however, both electrodes satisfy the biocompatibility requirements of IEC 10993-1.
5. The EMG electrodes for both devices furthermore satisfy the electrical and adhesion performance requirements of AAMI EC12.
6. Finally, the EMG electrode of the subject device exhibits same or better safety and performance characteristics (charge density current density and power density) at the skin/electrode interface than that of the reference device.

The comparative analysis presented above does not raise any new questions in terms of risk and performance of the subject device, and is supported by the performance data captured under paragraph 5.7.

5.7 Performance Testing

The following performance tests were conducted on the subject device in support of the claim for substantial equivalence:

1. Functional Performance Testing.
2. Electrical safety (in accordance with IEC 60601-1).
3. Electromagnetic compatibility (in accordance with IEC 60601-1-2 and IEC 60601-2-40).
4. Biocompatibility testing (in accordance with ISO10993-1).
5. Usability testing.
6. Battery life testing.
7. Tensile strength testing of the electrode.
8. Stimulation Performance Testing of the electrode (Charge Density, Current Density and Power Density)

The subject device met or exceeded the stated acceptance criteria for each performance test which were all confirmed to be the same or very similar to the performance specifications of the predicate device, and/or where relevant, to the reference device. The resultant test data therefore provided sufficient evidence to support the claim that the subject device is at least as safe and as effective as the predicate device in monitoring the muscle relaxation of a patient that has been subjected to the administration of a Neuromuscular Blocking Agent.

5.8 Clinical Performance

No clinical testing was conducted to demonstrate that the subject device is substantially equivalent to the predicate device, since the two devices were already proven to have similar

technological characteristics. There was no clinical testing conducted to demonstrate that the subject was substantially equivalent to the reference device, as the reference device has similar technological characteristics.

5.9 Conclusion (Statement of Equivalence)

A detailed comparative analysis involving the identified subject, predicate and references devices, has provided sufficient evidence in support of the following conclusion:

The subject device when compared to the predicate device and reference device has the same intended use, user profile and patient population, and the same or very similar technological characteristics. Differences in the technological characteristics of the two devices did not raise any new questions of safety and effectiveness, and the resultant test data from the performance tests, demonstrated that the subject device is at least as safe and effective as the reference device in terms of the use of EMG in NMT Monitoring applications.

There are no significant differences between the STIMPOD NMS450 Nerve Stimulator and the predicate and reference 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.