October 18, 2019

Senzime AB
% Elisa Maldonado-Holmertz
RA/QA Consultant
Obleix Consulting LLC
12416 Fairfax Ridge Place
Austin, Texas 78738

Re: K190795
Trade/Device Name: Tetragraph Neuromuscular Transmission Monitor
Regulation Number: 21 CFR 868.2775
Regulation Name: Electrical Peripheral Nerve Stimulator
Regulatory Class: Class II
Product Code: KOI
Dated: September 11, 2019
Received: September 12, 2019

Dear Elisa Maldonado-Holmertz:

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,

Todd Courtney
Assistant Director
DHT1C: Division of ENT, Sleep Disordered
Breathing, Respiratory and
Anesthesia 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K190795

Device Name
TetraGraph Neuromuscular Transmission Monitor

Indications for Use *(Describe)*

The TetraGraph Neuromuscular Transmission (NMT) Monitor is indicated for monitoring the relaxation of the patient when neuromuscular blockade is administered.

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.

Section 005 - 510(k) Summary

1. Submission Sponsor

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3. Date Prepared

15 October 2019

4. Device Identification

Type of 510(k) Submission:	Traditional
Trade or Proprietary Name:	TetraGraph Neuromuscular Transmission (NMT) Monitor (TetraGraph)
Common or Usual Name:	TetraGraph
Product Code:	KOI
Regulation Nr:	868.2775
Regulation Name:	Electrical peripheral nerve stimulator
Class of Device:	Class II
Panel:	Anesthesiology
Reason for Submission:	New device
Multiple Devices:	No; this is the only device in the submission

5. Legally Marketed Predicate and Reference Devices

Predicate Device- K051635, Datex Ohmeda S/5 NeuroMuscular Transmission Module, E-NMT (from GE Healthcare)
Reference Device - K992598, TOF-Watch SX (from Merck & Co, Inc. (Organon Teknika Corp.))

6. Device Description

The TetraGraph Neuromuscular Transmission (NMT) Monitor (TetraGraph) is a portable, battery-operated EMG-based neuromuscular transmission monitor for use perioperative and in recovery and critical care environments following or during the application of Neuromuscular block.

Neuromuscular Transmission (NMT) is the transfer of an electrical impulse between a motor nerve and its associated muscle. The NMT is blocked by neuromuscular blocking agents ("NMBAs") which cause transient muscle paralysis preventing the patient from moving and breathing spontaneously.

Muscle relaxation is used during general anesthesia to enable endotracheal intubation and mechanical ventilation and to provide optimal surgical conditions. Muscle relaxation may also be used in critical care during mechanical ventilation. In these circumstances, TetraGraph can be used as an objective monitor of neuromuscular transmission. TetraGraph undertakes this function by electrical stimulation of the peripheral nerve and directly measuring the evoked response of the muscles (Muscle Action Potential (MAP)), thus providing a quantitative and automatic measurement of muscle response to a stimulus using electromyography (EMG). The TetraGraph is a prescription-only medical device and is indicated for use in hospitals. TetraGraph supplements the use of clinical information/data obtained from other monitors, such as peripheral oxygen saturation (SpO2), end-tidal carbon dioxide (ETCO2), as well as clinical assessment, to determine the adequacy of ventilation.

The level of neuromuscular block is routinely measured by stimulating a peripheral nerve, usually in the forearm and by evaluating the muscle response typically in the thumb or little finger. The TetraGraph controls the level of electrical stimulation applied to the nerve and monitors the muscle response by the use of Electromyography (EMG) detected by electrodes on the muscle.

TetraGraph consists of the following main components:

<u>TetraGraph Monitor</u>
The TetraGraph Monitor is used to control the electrical stimulation and to measure the EMG-response. The Monitor is controlled via a touch screen and a power button. The

TetraGraph Monitor is connected to the electrode via a cable (the TetraCord Cable). The battery in the TetraGraph Monitor is charged via a communication port connected to a USB-supply adapter.

TetraSens Electrode
The TetraSens Electrode is a single-use electrode array. Each array includes two stimulating electrodes (applied along the ulnar nerve at the wrist) and two recording electrodes (applied on the hand). The TetraGraph Monitor can transmit stimulation pulses to the patient and can receive EMG signals via the electrode array. The electrodes are neither supplied sterile nor intended to be sterilized by the user.

The TetraSens Electrodes are sold separately from the TetraGraph monitor and are available in boxes of 20 pcs.

TetraCord Cable
The TetraCord Cable is connected to the TetraGraph Monitor via a port and is connected to the TetraSens Electrode via the cable connector at the other end of the TetraCord Cable. The TetraCord Cable is supplied in together with the TetraGraph monitor as part of the kit and can also be sold separately as a spare part.

TetraGraph Pole Clamp kit
A Pole clamp kit is available for mounting the TetraGraph on a pole stand. The kit includes a mounting device and an attachment to the TetraGraph. The Pole clamp kit is supplied separately from the TetraGraph kit.

Rechargeable lithium-polymer battery
A re-chargeable lithium-polymer battery is included in the TetraGraph, and also available as spare part. The rechargeable battery is charged using the USB power supply adapter.

USB power supply adapter and USB cable
The rechargeable battery is charged using the USB power supply adapter. The adapter is configured for local power outlets and connects to the TetraGraph using a USB cable. Data can also be transferred to a PC via the USB-port by using the USB-cable.

7. Indication for Use Statement

Indications for Use: The TetraGraph Neuromuscular Transmission (NMT) Monitor is indicated for monitoring the relaxation of the patient when neuromuscular blockade is administered.

8. Substantial Equivalence Discussion

A device comparison is made for the TetraGraph compared to the predicate device Datex-Ohmeda S/5 NeuroMuscular Transmission Module, E-NMT from GE Healthcare ("Datex-Ohmeda"). Datex-Ohmeda's existing 510(k) clearance (K051635) means it is legally marketed.

Intended use and indications for use, substantial equivalence discussion

The intended use for the predicate device (Datex-Ohmeda S/5 NeuroMuscular Transmission Module, E-NMT) is the same since the Regulation 868.2775 applies for both:

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.

	TetraGraph Neuromuscular Transmission (NMT) Monitor	**Datex-Ohmeda S/5TNI E-NMT module**
Indications for use	The TetraGraph Neuromuscular Transmission (NMT) Monitor is indicated for monitoring the relaxation of the patient when neuromuscular blockade is administered.	The Datex-Ohmeda S/5TNI E-NMT module is indicated for monitoring the relaxation of the patient and regional block stimulation for nerve location. The device is indicated for use by qualified medical personnel only.

Both devices are indicated for monitoring the muscle relaxation of the patient, which is TetraGraph's sole indication. Datex-Ohmeda also has a second indication: nerve location. However, TetraGraph has only one of the predicate device's two indications meaning that the subject device is compared to its predicate device with respect to their mutual indication only.

The predicate device states that it is indicated for use by qualified medical professionals only in its indications. However, TetraGraph is a prescription device, and thus, it is also limited to use by medical professionals. TetraGraph's indications for use statement and its device's labeling identify it as a prescription device. Thus, both devices have the same population of intended users. Senzime believes that TetraGraph's Rx designation in its indications for use statement and on its labeling conveys that limitation and that it would be redundant to identify its intended user population in the device's indications.

To summarize, the indications for use statement for the TetraGraph and its predicate device are not identical, but their mutual indication and common user population mean that they have the same intended use.

Technological Characteristics

Both TetraGraph and the predicate device measure muscle response using electromyography (EMG) and have reusable cables for the electrode connection. The electrode used for the stimulation are single-use. There are minor technological differences in number of electrodes and stimulation settings. Performance testing show that TetraGraph met all the acceptance criteria for this device, and which are the same or very similar to the predicate device's specifications. Thus, the test data demonstrate that TetraGraph is at least as safe and effective in monitoring the relaxation of the patient when neuromuscular blockade is administered as Datex-Ohmeda.

Substantial Equivalence Table:

The following Comparison of Characteristics Table compares the TetraGraph to the predicate device with respect to intended use, technological characteristics and principles of operation, providing more detailed information regarding the basis for the determination of substantial equivalence.

Table – Comparison of Characteristics

Trade Name	TetraGraph Neuromuscular Transmission Monitor	Datex-Ohmeda S/5 NeuroMuscular Transmission Module, E-NMT	TOF-Watch SX
Device	**SUBJECT**	**PREDICATE (K051635)**	**REFERENCE (K992598)**
Product Code	KOI	KOI	KOI
Device Class	Class II	Class II	Class II
Classification name	Electrical peripheral nerve stimulator	Electrical peripheral nerve stimulator	Electrical peripheral nerve stimulator
Regulation Number	868.2775	868.2775	868.2775
Classification Panel	Anesthesiology	Anesthesiology	Anesthesiology
Intended Use	The TetraGraph Neuromuscular (NMT) Monitor is an electrical peripheral nerve stimulator (neuromuscular blockade monitor) that is used to apply an electrical current to a patient to test the level of pharmacological effect of anesthetic drugs and gases.	Datex-Ohmeda is an electrical peripheral nerve stimulator (neuromuscular blockade monitor) that is used to apply an electrical current to a patient to test the level of pharmacological effect of anesthetic drugs and gases.	TOF-Watch is an electrical peripheral nerve stimulator (neuromuscular blockade monitor) that is used to apply an electrical current to a patient to test the level of pharmacological effect of anesthetic drugs and gases.
Indications for Use	The TetraGraph Neuromuscular Transmission (NMT) Monitor is indicated for monitoring the relaxation of the patient when neuromuscular blockade is administered.	The Datex-Ohmeda S/5TNI E-NMT module is indicated for monitoring the relaxation of the patient and regional block stimulation for nerve location. The device is indicated for use by qualified medical personnel only.	The TOF-Watch is an instrument for monitoring the neuromuscular transmission during surgery or in the intensive care unit by means of acceleromyography. The TOF-Watch is only to be operated by trained medical personnel.
Muscle movement detection technology	Electromyography (EMG)	Electromyography EMG Mechanomyography (MMG)	Acceleromyography (AMG)
Electrode Connection	Reusable Cable	Reusable Cable	Reusable Cable
Electrode for Stimulation	Single use electrode array (4 electrodes on an array)	Single use standard ECG electrodes (5 electrodes)	Single use standard ECG electrodes (3 electrodes)
Stimulation Patterns	Single Twitch (ST), Train-of-Four (TOF), Post-tetanic Count (PTC)	ST, TOF, PTC, DBS	TOF, PTC, DBS, 1Hz, 0,1 Hz, TET
Stimulation Current Range	10-60 mA	10 - 70 mA	0 - 60 mA
Stimulation Pulse Width	Square wave, constant current: 200 µs or 300 µs	Square wave, constant current: 100, 200 or 300 µs	200 µs or 300 µs

9. Performance Testing

Performance testing has been made for the TetraGraph which supports substantial equivalence between the TetraGraph and the predicate device.

The performance testing made for the device is summarized below:

- Software performance testing
- Electrical safety (in accordance with IEC 60601-1)
- Electromagnetic compatibility (in accordance with IEC 60601-1-2 and IEC 60601-2-40)
- Biocompatibility testing (in accordance with ISO10993-1)
- Thermal testing
- Mechanical strength
- Environmental testing
- Usability testing
- Shelf life testing
- Battery life testing
- Performance testing of electrodes; including tensile testing as well as electrical performance (as specified in the ANSI/AAMI EC12:2000 standard)

The performance testing show that TetraGraph met all of the acceptance criteria for this device, and which are the same or very similar to the predicate device's specifications. Thus, the test data demonstrate that TetraGraph is at least as safe and effective in monitoring the relaxation of the patient when neuromuscular blockade is administered as the predicate

10. Clinical Performance Data

There was no clinical testing required to demonstrate that TetraGraph is substantial equivalent to the Datex-Ohmeda Device, as the predicate has similar technological characteristics.

11. Statement of Substantial Equivalence

In summary, TetraGraph, compared to its predicate device, has the same intended use, one of the same indications for use, very similar technological characteristics, where the technological differences do not raise different questions of safety or effectiveness. Test data demonstrates that TetraGraph is at least as safe and effective as its predicate device for the same indications. Thus, TetraGraph is substantially equivalent to its predicate device.