August 17, 2022

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

Re: K220530
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: April 18, 2022
Received: April 19, 2022

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,

for Todd Courtney
Assistant 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)*
K220530

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.

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."

510(k) Summary

1 Submission Sponsor and contact person

Submisson Sponsor:
Senzime AB
Ulls väg 41, 756 51 Uppsala
Sweden
Johanna Faris, QA/RA Director
Email: johanna.faris@senzime.com
Phone number: +46 (0)705286330

Submission Correspondent:
Elisa Maldonado-Holmertz
RA/QA Consultant
Obelix Consulting, LLC
12416 Fairfax Ridge Place
Austin, TX 78738
Email: elisamh@obelixconsult.com
Tel number: +1 512 431 6069

2 Date Prepared

25 March 2022

3 Device Identification

Table 1. Device identification

The 510(k) number under which the legally marketed (existing) device was cleared	Traditional 510(k): K190795, cleared October 18, 2019
Type of this 510(k) Submission:	Traditional
Trade or Proprietary Name:	Tetragraph Neuromuscular Transmission Monitor
Common or Usual Name:	Tetragraph
Regulation Description:	Stimulator, Nerve, Peripheral, Electric
Regulation Classification:	868.2775
Product Code	KOI
Class of Device:	Class II
Review Panel:	Division of Anesthesia, Respiratory, and Sleep Devices (DHT1C)
Reason for Submission:	New accessories: electrode size and interface
Prior Related Submissions:	K190795 K220530 (Special 510(k) converted to Traditional 510(k))

Multiple Devices:	None; this is the only device in the submission

4 Legally Marketed Predicate Device

Predicate Device - K190795 Tetragraph Neuromuscular Transmission Monitor.

5 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.

The level of neuromuscular block is routinely measured by stimulating a peripheral nerve, by evaluating the muscle response. 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:

5.1 TetraGraph Monitor

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).

5.2 TetraSens Electrode

The TetraSens electrode is a single-use electrode array. Each array includes two stimulating electrodes and two recording electrodes. 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.

5.3 TetraSens Pediatric Electrode (new accessory to TetraGraph)

The TetraSens Pediatric electrode is a single-use electrode array. Each array includes two stimulating electrodes and two recording electrodes. 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 Pediatric electrodes are sold separately from the TetraGraph monitor and are available in boxes of 15 pcs.

5.4 Philips Interface (new and optional accessory to TetraGraph)

The Philips interface is a reusable dongle/cable to connect between TetraGraph and Philips patient monitor. Live measurement data is transmitted through the interface for display on the external patient monitor. The Philips Interface is neither supplied sterile nor intended to be sterilized by the user. This cable is not intended to have any patient contact during clinical application.

The Philips Interface Cable is an optional accessory to Tetragraph.

5.5 Pole clamp kit (optional accessory to TetraGraph)

The pole clamp kit is a reusable accessory to mount the TetraGraph monitor to a pole stand. The kit includes a mounting device and an attachment to the TetraGraph. This pole clamp kit is neither supplied sterile nor intended to be sterilized by the user. This accessory is not intended to have any patient contact during clinical application.

The Pole clamp kit is an optional accessory to TetraGraph.

6 Indication for Use Statement

The Indication for Use Statement is the same as K190795.

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

7 Substantial Equivalence Discussion

A device comparison is made between the TetraGraph and new accessory TetraSens Pediatric electrode and the predicate device TetraGraph and TetraSens electrode (K190795). No characteristics of TetraGraph monitoring system are changed due to the TetraGraph Philips Interface cable that allows for connection to an external Philips monitor.

TetraSens Pediatric electrode and TetraSens electrode (K190795) are substantially equivalent with minor dimension differences, minor material differences and labeling additions. TetraSens Pediatric electrode has the same target patient group and maximum stimulating energy as TOFscan (K172690). The other reference devices are the pediatric sensor for Phillips IntelliVue Patient Monitor (K122439 and K161531).

Philips Interface are substantially equivalent with Philips IntelliVue 4-Slot Module Rack FMX-4 (K210906) as both are intended to be connected to a Philips IntelliVue monitor to allow for display of data

7.1 Device Modifications and Comparison of Technological Characteristics with the predicate device

In this submission, a new electrode accessory called TetraSens Pediatric is introduced to the TetraGraph monitoring system. This electrode has the same indication for use, the same technological characteristics, and the same operation principle, compared to the electrode submitted in the predicate device, i.e. TetraSens. TetraSens electrode that is part of the cleared K190795 is still part of the system and is not changed. Both TetraSens Pediatric electrodes and the predicate TetraSens electrode are intended to be connected to TetraGraph with the same reusable cables. No software and hardware modification has been made to TetraGraph monitoring system due to the introduction of TetraSens Pediatric. There are minor technological differences in size of electrode and materials between TetraSens Pediatric electrode and predicate TetraSens electrode.

Substantial Equivalence Table:

The following Comparison of Characteristics Table compares the TetraGraph in this submission to the predicate TetraGraph (K190795) with respect to indication for use, technological characteristics, and principles of operation, providing more detailed information regarding the basis for the determination of substantial equivalence.

No characteristics of TetraGraph monitoring system are changed due to the Philips Interface cable that allows for connection to an external Philips monitor.

Table 2– Comparison of Characteristics between TetraGraph (subject device) and K190795 (predicate device)

Trade Name	**TetraGraph Neuromuscular Transmission Monitor**	**TetraGraph Neuromuscular Transmission Monitor**	**Comment**
Device	**SUBJECT (K220530)**	**PREDICATE (K190795)**	
Product Code	KOI	KOI	Same
Device Class	Class II	Class II	Same
Classification name	Electrical peripheral nerve stimulator	Electrical peripheral nerve stimulator	Same
Regulation Number	868.2775	868.2775	Same
Classification Panel	Anesthesiology	Anesthesiology	Same
Indications for Use	The TetraGraph Neuromuscular Transmission (NMT) Monitor is indicated for monitoring the relaxation of the patient when neuromuscular blockade is administered.	The TetraGraph Neuromuscular Transmission (NMT) Monitor is indicated for monitoring the relaxation of the patient when neuromuscular blockade is administered.	Same
Muscle movement detection technology	Electromyography (EMG)	Electromyography (EMG)	Same

Trade Name	TetraGraph Neuromuscular Transmission Monitor	TetraGraph Neuromuscular Transmission Monitor	Comment
Device	**SUBJECT**	**PREDICATE (K190795)**	
Electrode Connection	Reusable Cable	Reusable Cable	Same
Electrode for Stimulation	Single use electrode array (4 electrodes on an array) Smaller dimension of the electrode array for pediatric use	Single use electrode array (4 electrodes on an array)	Additional size Minor change in material used in TetraSense Pediatric electrode
Stimulation Patterns	Single Twitch (ST), Train-of-Four (TOF), Post-tetanic Count (PTC)	Single Twitch (ST), Train-of-Four (TOF), Post-tetanic Count (PTC)	Same
Stimulation Current Range	10-60 mA	10-60 mA	Same
Stimulation Pulse Width	Square wave, constant current: 200 µs or 300 µs	Square wave, constant current: 200 µs or 300 µs	Same

TetraSens Pediatric electrode has the same target patient group and maximum stimulating energy as TOFscan (K172690). The other reference devices are the pediatric sensor for Phillips IntelliVue Patient Monitor (K122439 and K161531).

Trade name	TetraSens Pediatric	TetraSens	ToFscan	IntelliVue Patient Monitors	
Device	**Subject device**	**Predicate device (K190795)**	**Reference device (K172690)**	**Reference device (K122439)**	**Reference Device (K161531)**
Product code	KOI	KOI	KOI	MHX (KOI)	MHX (KOI)
Patient population group	infant and Pediatric patients	Adult-size hand	Pediatric Hand sensor and electrodes connector,	"The NMT Module isintended to be used with adult and pediatric patients."	"The monitor is intended to be used for monitoring and recording of, and to generate alarms, for,multiple physiological parameters of adults, pediatrics, and neonates."

TetraGraph Philips Interface cable has same intended use as Philips IntelliVue 4-Slot Module Rack FMX-4 as both are intended to be connected to a Philips IntelliVue monitor to allow for display of data.

Trade name	**TetraGraph Philips Interface cable**	**Philips IntelliVue 4-Slot Module Rack FMX-4**
Device	**Subject device**	**Predicate device (K210906)**
Product code	KOI	MHX (KOI)
Outlet Port	Philip IntelliVue Monitor	Philip IntelliVue Monitor

7.2 Performance Testing

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

The performance testing made for the device is summarized below:

- Biocompatibility testing (in accordance with ISO 10993-1, including cytotoxicity, sensitization, and irritation)
- Testing of electrodes against ANSI/AAMI EC12: 2000 for Disposable ECG Electrodes
- EMG evoked response detection
- Electrode tensile strength
- Other performance testing was also completed and met all acceptance criteria

The performance testing on bench showed that the new TetraSens Pediatric electrode used with the 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.

7.3 Clinical Performance Data

There was no clinical testing required to demonstrate that TetraGraph with the new TetraSens Pediatric electrodes is substantial equivalent to the predicate device as the predicate has similar technological characteristics.

7.4 Statement of Substantial Equivalence

In summary, TetraGraph with the TetraSens Pediatric electrode, compared to its predicate (TetraGraph with the TetraSens electrode), has the same indications for use, same technological characteristics which do not raise questions of safety or effectiveness. Test data (shelf life, biocompatibility, software,

electrical and EMC, and performance) demonstrates that the TetraGraph with the new TetraSens Pediatric electrodes is at least as safe and effective as its predicate device for the same indication. Thus, TetraGraph with the TetraSens Pediatric electrode is substantially equivalent to its predicate device, TetraGraph with the TetraSens electrode.

The TetraGraph monitoring system, the related components, the accessories, and the software are substantially equivalent to its predicate device, TetraGraph (K190795).