May 22, 2026

Senzime AB
% Elisa Maldonado-Holmertz
RA/QA Consultant
Obelix Consulting, LLC
806 Jefferson St.
Bastrop, Texas 78602

Re: K261098
Trade/Device Name: TetraGraph Neuromuscular Transmission Monitor (SEN 2015)Accessories:TetraSens (SEN 2012)TetraSens Pediatric (SEN 2013)TetraSensitive (SEN 2016)TetraHub (SEN 2017)
Regulation Number: 21 CFR 868.2775
Regulation Name: Electrical Peripheral Nerve Stimulator
Regulatory Class: Class II
Product Code: KOI
Dated: April 24, 2026
Received: April 24, 2026

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Management System Regulation (QMSR) (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Bradley Q. Quinn -S

Bradley Quinn
Assistant Director
DHT1C: Division of Anesthesia,
Respiratory, and Sleep Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT, and Dental Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K261098

Please provide the device trade name(s).

TetraGraph Neuromuscular Transmission Monitor (SEN 2015)
Accessories:
TetraSens (SEN 2012)
TetraSens Pediatric (SEN 2013)
TetraSensitive (SEN 2016)
TetraHub (SEN 2017)

Please provide your Indications for Use below.

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

Please select the types of uses (select one or both, as applicable).	☒ Prescription Use (21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)
Please select the age group(s) for which the device(s) is to be used.	☐ Neonates/Newborns (Birth to < 29 days old) ☒ Infants (29 days old to < 2 years old) ☒ Children (2 years old to < 12 years old) ☒ Adolescents (12 years old to < 22 years old) ☒ Adults (22 years old and greater)

510(k) Summary

Submission Sponsor and contact person

Sponsor Contact: Johanna Faris, Head of QA/RA/S
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Date Prepared

20 May 2026

Device Identification

Table 1. Device identification

The 510(k) number under which the legally marketed (existing) device was cleared	Traditional 510(k): K220530, cleared August 17, 2022
Type of this 510(k) Submission:	Special
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
Multiple Devices:	None; this is the only device in the submission

Legally marketed predicate device

Predicate Device - K220530 Tetragraph Neuromuscular Transmission Monitor.

Device Description

The TetraGraph Neuromuscular Transmission (NMT) Monitor is a portable, battery- or wall power operated EMG-based neuromuscular transmission monitor for use in hospital settings including perioperative and in recovery and critical care environments following or during the application of Neuromuscular block. TetraGraph is intended to deliver stimulations to a nerve and record, measure, analyze and report muscle electrical activity to determine muscle function. TetraGraph is a prescription-only medical device.

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. NMBAs are commonly used during different clinical procedures, for example, 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. The level of neuromuscular block is routinely measured by stimulating a peripheral nerve. 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. The measured values that are displayed on TetraGraph provide the clinicians with an indication on the level of neuromuscular blockade in the patients.

TetraGraph consists of the following main components:

SEN 2015 TetraGraph Neuromuscular Transmission Monitor

Accessories:

SEN 2012 TetraSens

SEN 2013 TetraSens Pediatric

SEN 2016 TetraSensitive

Optional accessory:

SEN 2017 TetraHub

Intended Use

TetraGraph is intended to deliver stimulations to a nerve and record, measure, analyze and report muscle electrical activity to determine muscle function.

Indication for Use Statement

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

Intended Use and Indications for Use Comparison

Thes subject Intended Use and Indication for Use Statement is the same as predicate K220530.

Technological Comparison

Trade Name	TetraGraph Neuromuscular Transmission Monitor (Part number SEN 2015)	TetraGraph Neuromuscular Transmission Monitor (Part number SEN 2001)	Comment
Device	**SUBJECT (K261098)**	**PREDICATE (K220530)**	
Classification Panel	Anesthesiology	Anesthesiology	Same as its predicate device
Regulation Number	868.2775	868.2775	Same as its predicate device
Regulatory Class	Class II	Class II	Same as its predicate device

Trade Name	TetraGraph Neuromuscular Transmission Monitor (Part number SEN 2015)	TetraGraph Neuromuscular Transmission Monitor (Part number SEN 2001)	Comment
Device	**SUBJECT (K261098)**	**PREDICATE (K220530)**	
Product Code	KOI	KOI	Same as its predicate device
Intended use	TetraGraph is intended to deliver stimulations to a nerve and record, measure, analyze and report muscle electrical activity to determine muscle function.	TetraGraph is intended to deliver stimulations to a nerve and record, measure, analyze and report muscle electrical activity to determine muscle function.	Same as its predicate device
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 as its predicate device
Description of design	The TetraGraph Neuromuscular Transmission (NMT) Monitor (TetraGraph) is a portable EMG-based neuromuscular transmission monitor for use perioperative and in recovery and critical care environments following or during the application of Neuromuscular block.	The TetraGraph Neuromuscular Transmission (NMT) Monitor (TetraGraph) is a portable EMG-based neuromuscular transmission monitor for use perioperative and in recovery and critical care environments following or during the application of Neuromuscular block.	Same as its predicate device
Patient population group	All patient populations (except neonates)	all patient populations, (except neonates)	Same as its predicate device
Operating Principle	Electromyography (EMG)	Electromyography (EMG)	Same as its predicate device
Stimulation Patterns	Single Twitch (ST): pulse of 200 or 300µs duration at 10 or 5 seconds, Train-of-Four (TOF): 4 pulses of 200 or 300 µs duration at 2 Hz, repeated at user selected frequency of 15 seconds, 1 minute,5 minutes, 15 minutes or 60 minutes Post-tetanic Count (PTC): PTC consists of Tetanic Stimulation, a set of 250	Single Twitch (ST): pulse of 200 or 300 µs duration at 10 seconds Train-of-Four (TOF): 4 pulses of 200 or 300 µs duration at 2 Hz repeated at user selected frequency of 20 seconds, 1 minute, 5 minutes, 15 minutes or 60 minutes Post-tetanic Count (PTC): PTC consists of Tetanic Stimulation, a set of 250	Minor change in stimulation patterns. The differences do not raise new questions of safety or effectiveness.

Trade Name	TetraGraph Neuromuscular Transmission Monitor (Part number SEN 2015)	TetraGraph Neuromuscular Transmission Monitor (Part number SEN 2001)	Comment
Device	**SUBJECT (K261098)**	**PREDICATE (K220530)**	
	pulses (pulses at 50Hz over 5 seconds stimulated according to the current setting in the monitor) followed by up to 20 ST pulses at 1 Hz	pulses (pulses at 50Hz over 5 second at 50mA, 200 µs) followed by up to 20 ST pulses at 1 Hz	
Stimulating electrode placement	Peripheral Nerve	Peripheral Nerve	Same as its predicate device
Stimulation Current Range	10-80 mA	10-60 mA	Minor change in the stimulation current range. The differences do not raise new questions of safety or effectiveness.
Stimulation Pulse Width	Square wave, constant current: 200 µs or 300 µs	Square wave, constant current: 200 µs or 300 µs	Same as its predicate device
Electrode Connection	Reusable Cable	Reusable Cable	Same as its predicate device
Electrode for Stimulation	Single use electrode array (4 electrodes on an array)	Single use electrode array (4 electrodes on an array)	Same as its predicate device

There is no change in the technological characteristics for the subject TetraGraph monitoring system relative to the predicate TetraGraph monitoring system cleared under Senzime 510(k) K220530 supporting substantial equivalence.

Performance Testing

The safety and performance of the subject device, TetraGraph Neuromuscular Transmission Monitor, has been evaluated and verified in accordance with its performance specification and intended use to support a determination of substantial equivalence to the predicate device.

The following verification and validation testing was performed to support the modifications described in this Special 510(k) submission. All testing was completed and met predetermined acceptance criteria.

- Software Verification and Validation, including Cybersecurity mitigation

- Verification against IEC 60601-2-40
- Electrical safety testing against IEC 60601-1
- EMC testing against IEC 60601-1-2
- Electrode Verification testing

Performance testing demonstrates that the proposed device is as safe and effective, performs as well as the predicate, and is deemed substantially equivalent.

Clinical Performance Data

No clinical test was performed in support of this premarket notification.

Statement on Substantial Equivalence

Based on this, the proposed TetraGraph Neuromuscular Transmission Monitor is substantially equivalent to the predicate device.