July 10, 2026

Masimo Corporation
Monish Patel
Sr. Regulatory Specialist
52 Discovery
Irvine, California 92618

Re: K260880
Trade/Device Name: SedLine Sedation Monitor
Regulation Number: 21 CFR 882.1400
Regulation Name: Electroencephalograph
Regulatory Class: Class II
Product Code: OLW, OLT, OMC, ORT, GXY
Dated: June 5, 2026
Received: June 8, 2026

Dear Monish Patel:

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,

JAMES J. LEE -S

for 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.	K260880

Please provide the device trade name(s).

SedLine Sedation Monitor

Please provide your Indications for Use below.

The SedLine Sedation Monitor is intended to monitor the state of the brain by real-time data acquisition and processing of EEG signals. The SedLine Sedation Monitor is indicated for adult and pediatric patients (1 year of age and older) in the operating room (OR), intensive care unit (ICU), and clinical research laboratory.

The system includes the Patient State Index (PSi), a proprietary computed EEG variable that is related to the effect of anesthetic agents.

The PSi is indicated for use on adults sedated with the following agents: Alfentanil, Desflurane, Fentanyl, Isoflurane, Nitrous Oxide, Propofol, Remifentanil, and Sevoflurane.

The PSi is indicated for use on pediatrics 4 years and older when sedated with the following agents: Sevoflurane, Propofol.

The SedLine is only to be used with Masimo SedLine® sensors and cables. The use of any other sensor or cable is neither supported nor recommended by Masimo and could give erroneous results.

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)

MASIMO CORPORATION
52 Discovery
Irvine, CA 92618

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Submitter and Address of Manufacturing Facility:	Masimo Corporation 52 Discovery Irvine, CA 92618 Phone: (949) 297-7000 FAX: (949) 297-7592
Date:	July 08, 2026
Contact:	Monish Patel Sr. Regulatory Specialist Masimo Corporation Phone: (562) 239-1633
Trade Name:	Masimo SedLine Sedation Monitor
Common Name:	Index-generating electroencephalograph software
Classification Regulation/ Product Code:	21 CFR 882.1400/ OLW
Additional Classification/ Product Code(s):	21 CFR 882.1400/ OLT 21 CFR 882.1400/ OMC 21 CFR 882.1400/ ORT 21 CFR 882.1320/ GXY
Establishment Registration Number:	3011353843
Reason for Premarket Notification:	Expansion of indication for SedLine PSi to pediatrics
Predicate Device:	K203113, Masimo SedLine Sedation Monitor

1 Device Description

The Masimo SedLine Sedation Monitor is a 4-channel processed Electroencephalograph (EEG) monitor, which displays EEG waveforms, Density Spectral Array (DSA), Patient State Index (PSi), EMG Index, Suppression Ratio (SR) and Artifact (ARTF).

The Masimo SedLine Sedation Monitor includes the SedLine Module, SedLine EEG Sensor, and SedLine Patient Cable. The SedLine Module includes Masimo technology that processes the signal data collected from the SedLine sensor on the Host/Backboard device which provides the user interface.

As part of this submission, the indications for the SedLine Patient State Index (PSi) is being expanded to include use in the pediatric population.

Table 1.1-1 below provides the specifications for the Masimo SedLine Sedation Monitor:

Table 1.1-1: SedLine Sedation Monitor Specifications	
Feature	**Specification**
Display Range	
PSI	0 to 100
EMG	0 to 100%
SR	0 to 100%
ARTF	0 to 100%

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Table 1.1-1: SedLine Sedation Monitor Specifications	
Feature	**Specification**
DSA Amplitude (Left and Right)	-60 to 40 dB
SEFL/SEFR	0-30Hz
DSA Asymmetry	-100% to +100%
Electrode Impedance	0 to 65 kilohms
DSA frequency Range	0 to 30 Hz and 0 to 40 Hz
Resolution	
PSi	1
EMG	1%
SR	2%
ARTF	1%
DSA Amplitude (Left and Right)	≤1db
SEFL/SEFR	1 Hz
DSA Asymmetry	1%
Electrode Impedance	1 kilohms
General	
Visual/Audible Alarm	Host/Backboard Device (e.g., Masimo Root) provides the audible/visual alarms
Storage/Recording	Host/Backboard Device (e.g., Masimo Root) provides trend/data storage
Electrical	
DC Power	Host/Backboard Device (e.g., Masimo Root) provides DC power to SedLine Module
Interface	
SedLine Module Connection	Wired connection with Host/Backboard Device (e.g., Masimo Root)
Mechanical	
Module: Dimensions	1 3/10 in (3.3 cm) x 4 in (10.2 cm) x .8 in (2.0 cm)
Environmental	
Operating Conditions	
Temperature	+41°F to +104°F (+5°C to +40°C)
Humidity	15% to 95%, non-condensing
Storage Conditions	
Temperature	-40°F to +158°F (-40°C to +70°C)
Humidity	15% to 95%, non-condensing
Pressure	500 to 1060 mbar

2 Intended Use/ Indications for Use

The indications for use for Masimo SedLine Sedation Monitor is provided below:

The SedLine® Sedation Monitor is intended to monitor the state of the brain by real-time data acquisition and processing of EEG signals. The SedLine® Sedation Monitor is indicated for adult and pediatric patients (1 year of age and older) in the operating room (OR), intensive care unit (ICU), and clinical research laboratory.

The system includes the Patient State Index (PSi), a proprietary computed EEG variable that is related to the effect of anesthetic agents.

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The PSi is indicated for use on adults sedated with the following agents: Alfentanil, Desflurane, Fentanyl, Isoflurane, Nitrous Oxide, Propofol, Remifentanil, and Sevoflurane.

The PSi is indicated for use on pediatrics 4 years and older when sedated with the following agents: Sevoflurane, Propofol.

The SedLine® is only to be used with Masimo SedLine® sensors and cables. The use of any other sensor or cable is neither supported nor recommended by Masimo and could give erroneous results.

3 Technological Characteristics

Principle of Operation

There are no changes made to the principles of operation from the previous clearance under K203113.

SedLine still relies on the principle that brain activity results in electrical activity that can create detectable potential differences at the skin surface of the forehead that increases with increased brain activity and decreases with reduced brain activity. Same as the previous clearance, the PSi algorithm utilizes this relationship to establish characteristics of the EEG that can be quantified to establish multivariate combinations of quantitative EEG (qEEG) variables that are sensitive to the brain activity under changing levels of anesthesia.

Mechanism of Action for Achieving the Intended Effect

As part of this submission, Pediatric PSi will be displayed when a SedLine Pediatric sensor is connected to the SedLine Module. There are no other changes made to the mechanism of action from the previous clearance under K203113.

Same as the previous clearance, the SedLine EEG sensor is applied to the patient's forehead and connected to the SedLine Module using the SedLine patient cable. The SedLine Module is in turn connected to a host/ backboard device.

4 Discussion of Similarities and Differences Between Predicate and Subject Device

Similarities and Differences between Predicate and Subject Device

The subject device, SedLine Sedation Monitor, and predicate device, SedLine Sedation Monitor (K203113), have the following key similarities:

- Both devices have the same intended use.
- Both devices rely on the same principles of operations and mechanism of action.

The subject device, SedLine Sedation Monitor, and the predicate device, SedLine Sedation Monitor (K203113), have the following key differences:

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- Subject device adds expanded indications for PSi to include pediatric population.

Between the subject and the predicate device, there is no difference in the intended use. The difference between the subject and the predicate device is that the subject device expands the indications for use for PSi to pediatric patients. As part of the submission, data is provided to support the substantial equivalence of the subject device.

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Table 4-1 Comparison between Subject and Predicate Devices			
Feature	**Masimo SedLine Sedation Monitor** **Subject Device**	**Masimo SedLine Sedation Montor** **Primary Predicate Device (K203113)**	**Comparison to Predicate**
Classification	Index-generating electroencephalograph software	Index-generating electroencephalograph software	Same.
Regulation/ Product Code	21 CFR 882.1400/ OLW	21 CFR 882.1400/ OLW	Same.
Additional Classification Regulation/ Product Code(s)	21 CFR 882.1400/ OLT 21 CFR 882.1400/ OMC 21 CFR 882.1400/ ORT 21 CFR 882.1320/ GXY	21 CFR 882.1400/ OLT 21 CFR 882.1400/ OMC 21 CFR 882.1400/ ORT 21 CFR 882.1320/ GXY	Same.
Intended Use/ Indications for Use	The SedLine® Sedation Monitor is intended to monitor the state of the brain by real-time data acquisition and processing of EEG signals. The SedLine® Sedation Monitor is indicated for adult and pediatric patients (1 year of age and older) in the operating room (OR), intensive care unit (ICU), and clinical research laboratory. The system includes the Patient State Index (PSi), a proprietary computed EEG variable that is related to the effect of anesthetic agents. The PSi is indicated for use on adults sedated with the following agents: Alfentanil, Desflurane, Fentanyl, Isoflurane, Nitrous Oxide, Propofol, Remifentanil, and Sevoflurane. The PSi is indicated for use on pediatrics 4 years and older when sedated with the following agents: Sevoflurane, Propofol. The SedLine® is only to be used with Masimo SedLine® sensors and cables. The use of any other	The SedLine® Sedation Monitor is intended to monitor the state of the brain by real-time data acquisition and processing of EEG signals. The SedLine® Sedation Monitor is indicated for adult and pediatric patients (1 year of age and older) in the operating room (OR), intensive care unit (ICU), and clinical research laboratory. The system includes the Patient State Index (PSi), a proprietary computed EEG variable that is related to the effect of anesthetic agents. The PSi is indicated for use on adults sedated with the following agents: Alfentanil, Desflurane, Fentanyl, Isoflurane, Nitrous Oxide, Propofol, Remifentanil, and Sevoflurane. The PSi is not indicated for use in the pediatric population and is not displayed when using the pediatric sensors. The SedLine® is only to be used with Masimo SedLine® sensors and cables. The use of any other sensor or cable is neither supported nor recommended by Masimo and could give erroneous results.	Same. The subject device and the predicate device have the same intended use. The subject device is provided with expanded indications for PSi for use on pediatrics. Data is provided to support the substantial equivalence.

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Table 4-1 Comparison between Subject and Predicate Devices			
Feature	**Masimo SedLine Sedation Monitor Subject Device**	**Masimo SedLine Sedation Montor Primary Predicate Device (K203113)**	**Comparison to Predicate**
	sensor or cable is neither supported nor recommended by Masimo and could give erroneous results.		
Monitoring Parameters	Electrode Status, EEG Waveforms, Patient State Index (PSi), Density Spectral Array (DSA), Electromyography (EMG), Artifacts (ARTF), Suppression Ratio (SR), and Spectral Edge Frequency (SEFL/SEFR)	Electrode Status, EEG Waveforms, Patient State Index (PSi), Density Spectral Array (DSA), Electromyography (EMG), Artifacts (ARTF), Suppression Ratio (SR), and Spectral Edge Frequency (SEFL/SEFR)	Same.
Electrical			
Type of Power	Operates on low voltage DC provided through connection to host device.	Operates on low voltage DC provided through connection to host device.	Same.
Electrical Safety	IEC 60601-1	IEC 60601-1	Same.
EMC	IEC 60601-1-2	IEC 60601-1-2	Same.
Input/ Output Interface			
Type of Interface	MOC-9	MOC-9	Same.
Communication Type	Masimo Proprietary Protocol	Masimo Proprietary Protocol	Same
Physical Characteristics			
Dimensions	1 3/10 in (3.3 cm) x 4 in (10.2 cm) x .8 in (2.0 cm)	1 3/10 in (3.3 cm) x 4 in (10.2 cm) x .8 in (2.0 cm)	Same.
Performance Specifications – Display Range			
PSI	0 to 100	0 to 100	Same.
EMG	0 to 100%	0 to 100%	Same.
SR	0 to 100%	0 to 100%	Same.
ARTF	0 to 100%	0 to 100%	Same.
DSA Amplitude (Left and Right)	-60 to 40 dB	-60 to 40 dB	Same.
SEFL/SEFR	0-30Hz	0-30Hz	Same.
DSA Asymmetry	-100% to +100%	-100% to +100%	Same.
Electrode Impedance	0 to 65 kilohms	0 to 65 kilohms	Same.

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Table 4-1 Comparison between Subject and Predicate Devices			
Feature	**Masimo SedLine Sedation Monitor**	**Masimo SedLine Sedation Montor**	**Comparison to Predicate**
	Subject Device	**Primary Predicate Device (K203113)**	
DSA Frequency Range	0 to 30 Hz and 0 to 40 Hz	0 to 30 Hz and 0 to 40 Hz	Same.
Performance Specifications – Resolution			
PSI	1	1	Same.
EMG	1%	1%	Same.
SR	2%	2%	Same.
ARTF	1%	1%	Same.
DSA Amplitude (Left and Right)	≤1db	≤1db	Same.
SEFL/SEFR	1 Hz	1 Hz	Same.
DSA Asymmetry	1%	1%	Same.
Electrode Impedance	1 kilohms	1 kilohms	Same.
Environmental Specifications			
Operating conditions			
Temperature	+41°F to +104°F (+5°C to +40°C)	+41°F to +104°F (+5°C to +40°C)	Same.
Humidity	15% to 95%, non-condensing	15% to 95%, non-condensing	Same.
Storage conditions			
Temperature	-40°F to +158°F (-40°C to +70°C)	-40°F to +158°F (-40°C to +70°C)	Same.
Humidity	15% to 95%, non-condensing	15% to 95%, non-condensing	Same.
Pressure	500 to 1060 mbar	500 to 1060 mbar	Same.
Mode of Operation per IEC 60601-1			
Mode of Operation	Continuous	Continuous	Same.

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5 Performance Data

As part of this submission, clinical performance data are provided to support the expanded indications for SedLine PSi.

Performance Bench Testing

No performance bench testing was provided as part of this submission as there were no changes made to the subject device.

Biocompatibility Testing

No biocompatibility testing was provided as part of this submission as there were no changes made to the patient contacting materials of the subject device.

Electromagnetic Compatibility, Electrical Safety, Environmental, Mechanical and Cleaning

No electrical safety, environmental, mechanical, and cleaning testing was included as part of this submission as there were no hardware changes made to the subject device.

Software Verification and Validation Testing

No software verification and validation testing were provided as part of this submission as there were no software changes made to the subject device.

Wireless Testing

No wireless testing was included as part of this submission as there were no changes to the wireless capabilities of the subject device.

Human Factors and Usability Testing

No human factors and usability testing was included as part of this submission as there were no changes made to the user interface of the subject device.

Clinical Testing

To support the expanded indications for SedLine Pediatric PSi, clinical data collected on 169 pediatrics was analyzed. The analysis was evaluated for performance of Pediatric PSi against references of evidence of burst suppression (for too deep sedation), manual sedation scoring (UMSS), and anesthesia stages. The results from the studies are supportive of the responsiveness of Pediatric PSi and the substantial equivalence of the subject device.

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6 Conclusion

Based on the data provided as part of this submission, the subject device was found to be substantially equivalent.