February 25, 2022

Masimo Corporation
Sindura Penubarthi
Regulatory Affairs Manager
52 Discovery
Irvine, California 92618

Re: K203113
Trade/Device Name: Masimo SedLine Sedation Monitor and Accessories
Regulation Number: 21 CFR 882.1400
Regulation Name: Electroencephalograph
Regulatory Class: Class II
Product Code: OLW, OLT, GXY, OMC, ORT
Dated: December 15, 2021
Received: December 17, 2021

Dear Sindura Penubarthi:

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 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)*
K203113

Device Name
Masimo SedLine® Sedation Monitor and Accessories

Indications for Use *(Describe)*
SedLine Sedation Monitor

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.

SedLine Sensor

The RD SedLine Pediatric Sensor electrodes are applied directly to the patient's skin to enable the recording of electrophysiological signals (e.g., EEG). The RD SedLine Pediatric Sensors are indicated for pediatric patients (1 to 17 years).

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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Submitter and Address of Manufacturing Facility:	Masimo Corporation 52 Discovery Irvine, CA 92618 Phone: (949) 297-7982 FAX: (949) 297-7199
Date:	10/13/2020
Contact:	Sindura Penubarthi Regulatory Affairs Senior Manager Masimo Corporation Phone: (949) 396-4041 spenubarthi@masimo.com
Trade Name:	Masimo SedLine Sedation Monitor and Accessories
Common Name:	Brain Function Monitor
Classification Regulation/ Product Code:	21 CFR 882.1400, Class II/OLW
Additional Product Code:	OLT, OMC, ORT, GXY
Establishment Registration Number:	3011353843
Reason for Premarket Notification:	Expansion to the indications for use and introduction of Pediatric Sensor
Predicate Device:	K172890 - Masimo SedLine® Sedation Monitor
Reference Predicate:	K072286 – Aspect Medical System, Inc, BISx
Performance Standards	No performance standards for the above device have been promulgated pursuant to Section 514 of the Food and Drug Administration Modernization Act of 1997 (FDAMA)

1. Device Description

The Masimo SedLine® Sedation Monitor is a patient-connected, 4-channel processed Electroencephalograph (EEG) monitor. It displays electrode status, EEG waveforms, Density Spectral Array (DSA), and 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.

The performance specifications for SedLine are included in Table 1.1 below:

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TABLE 1.1 SedLine Specifications	
FEATURE	**SPECIFICATION**
Display Range	
PSI	0 to 100
EMG	0 to 100%
SR	0 to 100%
ARTF	0 to 100%
DSA Amplitude (Left and Right)	-60 to 40 dB
SEFL/SEFR	0-30Hz
DSA Asymmetry	-100% to +100%
Electrode Impedance	0 to 65 kohms
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 kohms
General	
Visual/Audible Alarm	Host/Backboard Device (Masimo Root Monitoring System) provides the audible/visual alarm in compliance with IEC60601-1-8
Storage/Recording	Host/Backboard Device (Masimo Root Monitoring System) provides trend/data storage
Electrical	
DC Power	Host/Backboard Device (Masimo Root Monitoring System) provides DC power to SedLine Module
Interface	
SedLine Module Connection	MOC-9 interface with Host/Backboard device (Masimo Root Monitoring System)
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	15–95%, non-condensing
Pressure	500 to 1060 mbar

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Table 1.2 SedLine Pediatric Sensor Specifications	
Application site	Forehead
Intended patient population	1 to 17 years
Mechanical	
Dimensions	7" by 5.5"
Biocompatibility	ISO 10993-1
Environmental specifications	
Operating Temperature	10°C to 40°C
Storage Temperature	-40°C to +70°C
Humidity	10% to 95% non-condensing

1.1 Intended Use

1.1.1 *Intended 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 computed values are displayed on a Host/Backboard monitor such as the Masimo Root Monitoring System.

1.1.2 *Indications for Use*

SedLine Sedation Monitor

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.

SedLine Sensor

The RD SedLine Pediatric Sensor electrodes are applied directly to the patient's skin to enable the recording of electrophysiological signals (e.g., EEG). The RD SedLine Pediatric Sensor is indicated for pediatric patients (1 to 17 years).

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1.2 Technological Characteristics

1.2.1 *Principle of Operation*

The SedLine is based upon the principle that brain activity results in electrical activity that can create detectable potential difference at the skin surface of the forehead that increase with increased brain activity and decrease with reduced brain activity. The Patient State Index (PSi) utilizes this relationship to establish characteristics of the EEG that can be quantified to establish multivariate combinations of quantitative electroencephalogram (QEEG) variables that are sensitive to the brain activity under changing levels of anesthesia. The PSi is the result of a proprietary computation that combines weighted quantitative values reflecting many dimensions of brain electrical activity, such as: (1) changes in power in various EEG frequency bands, (2) changes in symmetry and synchronization between critical brain regions, and (3) the inhibition of regions of the frontal cortex.

The PSi is computed continuously from monitored changes in the QEEG when the sensor is applied. The PSi values are intended to provide information on the changes in sedation with the lower values reflecting lower levels of brain activity and deeper levels of sedation.

1.2.2 *Mechanism of Action for Achieving the Intended Effect*

The SedLine EEG Sensor is noninvasively applied to the patient's forehead and is connected to the SedLine Module using a SedLine patient cable. The SedLine Module connects to a Host/Backboard device through an electrical connection. The SedLine EEG Sensor detects the potential differences at the forehead which are transmitted to the SedLine Module, which processes those potential differences as the EEG waveform and the analysis of the signal characteristics to be displayed on the Host/Backboard device.

To accommodate the smaller foreheads of the pediatric patient population, the SedLine is provided with a smaller form factor sensor more tailored to pediatric patients.

1.2.3 *Summary of Technological Characteristics of Subject Device Compared to Predicate Device*

The subject device, SedLine® Sedation Monitor, and the predicate device, SedLine® Sedation Monitor (K172890), have the following key similarities:

- Both devices have the same intended use to monitor the state of the brain by real-time data acquisition and processing of EEG signals;
- Both devices rely on the same principles of operations;
- Both devices have the same environmental specifications;
- Both devices utilize the same sensor materials;
- Both devices provide similar displays of EEG features.

The subject device and the predicate device, SedLine® Sedation Monitor (K172890), have the following key differences:

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- Subject device includes the indication for pediatric patients 1 to 17 years of age;
- Subject device includes pediatric sensors that have a smaller sensor form factor.

The main difference between the subject device and the predicate device (K172890) is the expansion of the indications to support the pediatric population and the addition of pediatric sensors that have a smaller form factor compared to the adult sensor and a pediatric sensor that is sized equivalent to the adult sensor. To support the substantial equivalence of the subject device non-clinical testing was performed.

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TABLE 5 SUBSTANTIAL EQUIVALENCE			
FEATURE	**Masimo SedLine® Sedation Monitor**	**Masimo SedLine® Sedation Monitor**	**Comparison**
510(k) Number	**Subject device**	**Predicate device (K172890)**	
General Information			
Intended Use /Indications for Use (IFU)	The SedLine® Sedation Monitor is intended to monitor the state of the brain by real-time data acquisition and processing of EEG signals. The system includes the Patient State Index (PSi), a proprietary computed EEG variable that is related to the effect of anesthetic agents. 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 PSi is indicated for use on adults sedated with the following agents: Alfentanil, Desflurane, Fentanyl, Isoflurane, Nitrous Oxide, Propofol, Remifentanil, and Sevoflurane. 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.	The SedLine Sedation Monitor is indicated for use in the operating room (OR), intensive care unit (ICU), and clinical research laboratory. It is intended to monitor the state of the brain by real-time data acquisition and processing of EEG signals for adult patients (18 years of age and older). The system includes the Patient State Index (PSI), a proprietary computed EEG variable that is related to the effect of anesthetic agents. The agents include: Alfentanil, Desflurane, Fentanyl, Isoflurane, Nitrous Oxide, Propofol, Remifentanil, and Sevoflurane.	Added the indication for pediatrics and the specific use of SedLine with Masimo SedLine sensors and cables.

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TABLE 5 SUBSTANTIAL EQUIVALENCE			
FEATURE	**Masimo SedLine® Sedation Monitor**	**Masimo SedLine® Sedation Monitor**	**Comparison**
510(k) Number	**Subject device**	**Predicate device (K172890)**	
	SedLine Sensor The RD SedLine Pediatric Sensor electrodes are applied directly to the patient's skin to enable the recording of electrophysiological signals (e.g., EEG). The RD SedLine Pediatric Sensors are indicated for pediatric patients (1 to 17 years).		
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
Classification Regulation/ Product Code	21 CFR 882.1400,Class II/OLW	21 CFR 882.1400,Class II/OLW	Same
Additional Product Codes	OLT, OMC, ORT, GXT	OLT, OMC, ORT, GXT	Same
Principle of Operation	The SedLine is based upon the principle that brain activity results in electrical activity that can be create detectable potential difference activity at the skin surface of the forehead that increase with increased brain activity and decrease with reduced brain activity. The Patient State Index (PSi) utilizes this relationship	The SedLine is based upon the principle that brain activity results in electrical activity that can be create detectable potential difference activity at the skin surface of the forehead that increase with increased brain activity and decrease with reduced brain activity. The Patient State Index (PSi) utilizes this relationship	Same

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TABLE 5 SUBSTANTIAL EQUIVALENCE			
FEATURE	**Masimo SedLine® Sedation Monitor**	**Masimo SedLine® Sedation Monitor**	**Comparison**
510(k) Number	**Subject device**	**Predicate device (K172890)**	
	to establish characteristics of the EEG that can be quantified to establish multivariate combinations of quantitative electroencephalogram (QEEG) variables that are sensitive to the brain activity under changing levels of anesthesia. The PSi is the result of a proprietary computation that combines weighted quantitative values reflecting many dimensions of brain electrical activity, such as: (1) changes in power in various EEG frequency bands, (2) changes in symmetry and synchronization between critical brain regions, and (3) the inhibition of regions of the frontal cortex. The PSi is computed continuously from monitored changes in the QEEG when the sensor is applied. The PSi values are intended to provide information on the changes in sedation with the lower values reflecting lower levels of brain activity and deeper levels of sedation.	to establish characteristics of the EEG that can be quantified to establish multivariate combinations of quantitative electroencephalogram (QEEG) variables that are sensitive to the brain activity under changing levels of anesthesia. The PSi is the result of a proprietary computation that combines weighted quantitative values reflecting many dimensions of brain electrical activity, such as: (1) changes in power in various EEG frequency bands, (2) changes in symmetry and synchronization between critical brain regions, and (3) the inhibition of regions of the frontal cortex. The PSi is computed continuously from monitored changes in the QEEG when the sensor is applied. The PSi values are intended to provide information on the changes in sedation with the lower values reflecting lower levels of brain activity and deeper levels of sedation.	
Function			
EEG Data Display	EEG Waveform, DSA	EEG Waveform, DSA	Same
PSi Algorithm	Adult	Adult	Same
Electrical			

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TABLE 5 SUBSTANTIAL EQUIVALENCE			
FEATURE	**Masimo SedLine® Sedation Monitor**	**Masimo SedLine® Sedation Monitor**	**Comparison**
510(k) Number	**Subject device**	**Predicate device (K172890)**	
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
Mechanical			
Overall Dimensions	4 by 1.3 by 0.8 in (10.2 by 3.3 by 2 cm)	4 by 1.3 by 0.8 in (10.2 by 3.3 by 2 cm)	Same
Environmental			
Operating Temperature	5°C to 40°C	5°C to 40°C	Same
Storage Temperature	-40°C to 70°C	-40°C to 70°C	Same
Humidity	15-95% non-condensing	15-95% non-condensing	Same

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2. Performance Data

Biocompatibility Testing

Biocompatibility testing was not required for this submission as there was no change to the materials from the previously cleared adult SedLine sensor (K172890). The patient contacting materials were previously evaluated and found to be biocompatible in accordance with ISO 10993. Since there was no change to the patient contacting parts, additional biocompatibility testing was not conducted.

Electromagnetic Compatibility, Electrical Safety, Environmental, Mechanical and Cleaning

Electrical Safety, Environmental and Mechanical testing for the pediatric sensor was included in this submission.

Additional Electrical, Electromagnetic, Environmental, Mechanical and cleaning for this submission was not required as there was no change to the components from the previously cleared SedLine module (K172890).

Software Verification and Validation Testing

As part of this submission, additional Software verification and validation testing was conducted and documented as recommended by FDA's Guidance, *Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices*, dated May 11, 2005. The software for this device was still considered a "moderate" level of concern. The testing was found to support the substantial equivalence of the subject device.

Wireless and Cybersecurity Testing

Additional Wireless and Cybersecurity testing was not required as part of this submission as there were no changes to the wireless capabilities or communication capabilities of the subject device from the previously cleared SedLine sedation monitor (K172890). As a result, the acceptability of the wireless and cybersecurity risks for the subject device were determined based on the testing previously conducted as part of the predicate device clearance.

Human Factors Usability Testing

Additional Human Factors and Usability was not required as part of this submission as there was no change to the critical user related tasks or need for additional usability risk mitigations for the subject device from the previously cleared predicate device SedLine Sedation monitor (K172890). The human factor and usability consideration are the same as the previously cleared. As a result, the acceptability of the Human factors/ Usability risk for the subject device was determined based upon the testing conducted as part of the predicate device. The cleared predicate SedLine Sedation monitor had previously been tested in accordance with the FDA Guidance, *Applying Human Factors and Usability Engineering to Medical Devices, February 3, 2016*.

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3. Non-clinical Performance Testing

Non-clinical performance testing was performed for SedLine monitoring system. The non-clinical testing was conducted in accordance with Masimo requirements to ensure that the specifications of the subject device were met. The following non-clinical testing was performed:

- Software verification and validation testing per FDA Software Guidance
- Mechanical and Environmental Testing

The testing was found to support the expansion to the indications for use and do not raise different questions of safety and effectiveness of the device.

4. Conclusion

The data provided as part of this submission supports the substantial equivalence of the subject device.