January 26, 2018

Masimo Corporation
Matthew Tiacharoen
Regulatory Affairs Specialist II, Regulatory Affairs
52 Discovery
Irvine, California 92618

Re: K172890
Trade/Device Name: SedLine Sedation Monitor
Regulation Number: 21 CFR 882.1400
Regulation Name: Electroencephalograph
Regulatory Class: Class II
Product Code: OLW, GXY, OLT, OMC, ORT
Dated: December 22, 2017
Received: December 26, 2017

Dear Matthew Tiacharoen:

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. 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); good

manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Tara A. Ryan -S

Digitally signed by Tara A. Ryan -S
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, cn=Tara A. Ryan -S, 0.9.2342.19200300.100.1.1=1300030749
Date: 2018.01.26 14:48:19 -05'00'

for
Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
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)*
K172890

Device Name
SedLine Sedation Monitor

Indications for Use *(Describe)*
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 agents include: Alfentanil, Desflurane, Fentanyl, Isoflurane, Nitrous Oxide, Propofol, Remifentanil, and Sevoflurane. The SedLine Sedation Monitor is intended for use with adult patients (18 years of age and older) in the operating room (OR), intensive care unit (ICU), and clinical research laboratory.

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.

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Irvine, CA 92618

Section 5. 510(k) Summary

Submitter and Address of Manufacturing Facility:	Masimo Corporation 52 Discovery Irvine, CA 92618 Phone: (949) 297-7982 FAX: (949) 297-7199
Date:	January 26, 2018
Contact:	Matthew Tiacharoen Regulatory Specialist II, Regulatory Affairs
Trade Name:	SedLine Sedation Monitor
Common Name:	Brain Function Monitor
Classification Regulation/ Product Code:	21 CFR 882.1400, Class II/OLW
Additional Product Codes:	GXY,OLT, OMC, ORT
Establishment Registration Number:	2031172
Reason for Premarket Notification:	Device modification
Predicate Device:	K140188 - Masimo Root Monitoring System
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)

5.1 Device Description

SedLine® Sedation Monitor is a patient-connected, 4-channel processed Electroencephalograph (EEG) monitor designed specifically for intraoperative or intensive care use. It displays electrode status, EEG waveforms, Density Spectral Array (DSA), and Patient State Index (PSI), EMG Index, Suppression Ratio (SR) and Artifact (ARTF).

The operator controls the unit using menus and dedicated buttons to select various display options. The system consists of 4 major components: Root, SedLine Module, SedLine Patient Cable, and SedLine Sensor.

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Note: For clarification, the purpose of this submission is to demonstrate that the subject device, SedLine® Sedation Monitor, is the substantially equivalent to the predicate device's SedLine Module.

5.2 Significant Physical and Performance Characteristics of the Device

The device specifications are shown below for the general functions of the subject device.

TABLE 5.2 SedLine® Sedation Monitor Specifications	
FEATURE	**SPECIFICATION**
Display	
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
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 KOhm
General	
Visual/audible alarm	Host/Backboard Device (Masimo Root Monitoring System) is IEC60601-1-8 compliant per K140188
Storage/recording	Masimo Root Monitoring System has trend/data storage per K140188
Electrical	
AC Power	Host/Backboard Device (Masimo Root Monitoring System) provides AC power per K140188
Rechargeable battery	Host/Backboard Device (Masimo Root Monitoring System) provides internal battery power per K140188
Interface	
SedLine Module Connection	MOC-9 interface with Host/Backboard device (Masimo Root Monitoring System, per K140188)

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TABLE 5.2 SedLine® Sedation Monitor Specifications	
FEATURE	**SPECIFICATION**
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

5.3 Intended Use

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. The system includes the Patient State Index (PSI), a proprietary computed EEG variable that is related to the effect of anesthetic agents. The computed values are displayed on a Host/Backboard monitor such as the Masimo Root Monitoring System (K140188).

5.4 Indications For Use

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.

Note: The Indication for Use is the same as the SedLine Sedation Monitor, cleared under K140188, with the exception of identification of anesthetic agents used for validation and the intended use population age.

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5.5 Technological Characteristics

5.5.1 Principle of Operation

The Patient State Index (PSI) formula was constructed based upon multivariate combinations of quantitative electroencephalogram (QEEG) variables found to be sensitive to changes in the level of anesthesia but insensitive to the specific substances producing such changes. The PSI is the result of a complex 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 from continuously monitored changes in the QEEG during surgery, using statistical analysis to estimate the likelihood that the patient is anesthetized. The SedLine performs these computations automatically on the continuously recorded EEG after automatic removal of data contaminated with artifact from physiological and environmental signals. The computed PSI is periodically updated, displayed in numeric form, and presented in a color-coded trend graphic for monitoring the effect of certain anesthetics on the state of the brain.

5.5.2 Mechanism of Action for Achieving the Intended Effect

The SedLine EEG Sensor is noninvasively applied to the patient on one end. The other end of the SedLine EEG Sensor connects to the SedLine Module. In turn, the SedLine Module connects to a Host/Backboard device. The SedLine EEG Sensor collects patient EEG signals which are processed by the SedLine Module and displayed on the Host/Backboard device.

5.5.3 Summary of Technological Characteristics of Subject Device Compared to Predicate Device

The subject device, SedLine® Sedation Monitor, and the predicate device, Masimo Root Monitoring System (K140188), have the following key similarities:

- Both devices have the same parameters to measure patient sedation state;
- Both devices display their calculated values on a Host/Backboard device (Masimo Root Monitoring System);
- Both devices have the same indications for use;
- Both devices have the same intended use;
- Both devices have the same measurement site;

Section 5. 510(k) Summary

- Both devices include EEG sensors and patient cables.

The subject device and the predicate device, Root Monitoring System (K140188), differ only in the SedLine software. The differences are:

- An optional additional DSA display is now available that uses a multi-taper window EEG to display the spectral waveform;
- Modified Patient State Index (PSI) algorithm.

5.5.4 Non-clinical Testing

See below for the non-clinical testing that was completed.

- Electrical safety testing per IEC 60601-1
- EMC testing per IEC 60601-1-2
- Alarm testing per IEC60601-1-8
- Usability testing per FDA Human Factors and Usability Draft Guidance
- Software verification per FDA Software Guidance
- Mechanical Testing per EN 60601-2-26
- Environmental testing per EN 60601-2-26

The results demonstrate that all requirements and performance specifications were satisfied, and that the subject device is substantially equivalent to the predicate device.

The multi-taper DSA evaluation was conducted as part of the "Software verification per FDA Software Guidance." The tests validated DSA by comparing multi-taper DSA against the predicate's Hanning DSA, both computed for a known input signal. The following functionality were tested for multi-taper DSA:

- Dynamic range of the power spectrum,
- Frequency range,
- Spectral Edge Frequency, and
- High-contrast feature of the multi-taper DSA against the predicate's Hanning DSA.

5.5.5 Clinical Testing

Validation of the subject algorithm was performed by retrospective analysis of the clinical data in 100 surgical patients (age: 18-77 years, male/female: 26/74). The

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subject PSi algorithm was compared to the predicate PSi algorithm. The clinical data was collected at the operating room from three different hospitals. Clinical data used for the analysis includes continuous EEG, anesthetic drug dose information, and other physiological vital signs such as mean arterial blood pressure and heart rate.

5.5.6 Conclusion

The clinical and non-clinical testing provided in this 510(k) submission demonstrates that the subject device, SedLine® Sedation Monitor, is substantially equivalent to its predicate.