DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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November 23, 2016

Masimo Corporation
Marguerite Thomlinson
Senior Director, Regulatory Affairs
52 Discovery
Irvine, California 92618

Re: K160940
Trade/Device Name: Masimo Disposable Transflectance Forehead Sensor
Regulation Number: 21 CFR 870.2700
Regulation Name: Oximeter
Regulatory Class: Class II
Product Code: DQA
Dated: October 24, 2016
Received: October 27, 2016

Dear Marguerite Thomlinson:

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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Tina Kiang -S

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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K160940

Device Name

Masimo Disposable Transflectance Forehead Sensors

Indications for Use *(Describe)*

The Masimo Disposable Transflectance Forehead Sensors are indicated for continuous noninvasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate. The Masimo Disposable Transflectance Forehead Sensors are intended for use with adult and pediatric patients, weighing greater than 10 kg, who are well or poorly perfused in healthcare environments.

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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MASIMO CORPORATION
52 Discovery
Irvine, CA 92618

Section 5. 510(k) Summary

Submitter and Address of Manufacturing Facility:	Masimo Corporation 52 Discovery Irvine, CA 92618 Phone: (949) 297-7000 FAX: (949) 297-7592
Date:	November 21, 2016
Contact:	Marguerite Thomlinson Senior Director, Regulatory Affairs
Trade Name:	Masimo Disposable Transflectance Forehead Sensors
Common Name:	Oximeter
Classification Regulation/ Product Code:	21 CFR 870.2700, Class II/DQA
Establishment Registration Number:	2031172
Reason for Premarket Notification:	New Device
Predicate Device:	K032551, Masimo LNOP TF-1 Reusable Transflectance Sensor
Performance Standards	No performance standards for the above device have been promulgated pursuant to Section 514.

Device Description

The subject device, Masimo Disposable Transflectance Forehead Sensor (Forehead Sensor), is a single-use sensor and is supplied non-sterile. The sensor is available in two configurations, consisting of the LNCS TFA-1 with the DB9 sensor connector and the M-LNCS TFA-1 with the M15 sensor connector. The different sensor connectors allow for sensor connection to instruments with corresponding mating DB9 or M15 connectors. The subject device shall also be available with RD sensor connector. The subject device is intended to be used with instruments that include Masimo SET technology for the monitoring of:

- *Functional Oxygen Saturation of Arterial Hemoglobin (SpO2):* The amount of oxyhemoglobin expressed a percentage of the hemoglobin that is available

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- *Pulse Rate (PR):* Measured in beats per minute (BPM) is based on the optical detection of peripheral flow pulse
- *Perfusion Index (PI):* The ratio of the pulsatile blood flow to the non-pulsatile or static blood in peripheral tissue
- *Pleth Variability Index (PVI):* Measure of dynamic changes in perfusion index that occur during the respiratory cycle.

The Masimo SET technology is provided by the Masimo SET or Masimo Rainbow SET technology board, which is included in Masimo pulse oximeter instruments, Masimo pulse CO-oximeter instruments and third-party multi-parameter instruments.

The specifications of the Forehead Sensor are listed in the table below.

Forehead Sensor Specifications	
Features	**Specifications**
Patient population	Adults and pediatrics > 10 kg
Measurement site	Forehead
Type of use	Single-use
Sterility	Supplied non-sterile
Accuracy*	
SpO2, no motion	70-100 ± 2 %
SpO2, low perfusion	70-100 ± 2 %
Pulse Rate, no motion	25-240 ± 3 bpm
Pulse Rate, low perfusion	25-240 ± 3 bpm
Mechanical	
Sensor dimensions/weight	Approximately 2.5 x 1.5 in/ 1.0 oz (without cable)
Sensor cable length	36 in, nominal
Patient-contacting materials	ISO-10993 compliant
Environmental	
Storage temperature	-40°C to +70°C
Operating temperature	+5°C to +40°C
Humidity	10-95% humidity, non-condensing

*Accuracy was determined in terms of Arms (accuracy root mean square) per ISO-80601-2-61.

Intended Use/Indications for Use

The Masimo Disposable Transflectance Forehead Sensors are indicated for continuous noninvasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate. The Masimo Disposable Transflectance Forehead Sensors are intended for use with adult and pediatric patients, weighing greater than 10 kg, who are well or poorly perfused in healthcare environments.

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Technological Characteristics

Principle of Operation

The subject device, Forehead Sensor, is a pulse oximetry sensor which is governed by the following principles:

- Oxyhemoglobin (oxygentated blood) and deoxyhemoglobin (non-oxygenated blood) differ in their absorption of red and infrared light (spectrophotometry).
- The amount of arterial blood in tissue changes with a person's pulse (photoplethysymography). Therefore, the amount of light absorbed by the varying quantities of arterial blood changes as well.

Mechanism of Action for Achieving the Intended Effect

The Forehead Sensor is placed on the patient forehead and secured with a headband. The other end of the sensor is connected to a patient cable, which in turn is connected to a pulse oximeter. The instrument is turned on when use begins. Once use is complete, the user turns the instrument power "off" and removes the sensor from the patient.

Summary of Technological Characteristics of Subject Device Compared to Predicate Device

Similarities and Differences between Subject Device and Predicate Device (K032551)

The subject device, Forehead Sensor, and the predicate (K032551) have the following key similarities:

- Both devices have the same intended use of pulse oximetry measurements under no motion and low perfusion conditions;
- Both devices have the same forehead measurement site;
- Both devices are supplied non-sterile; and
- Both devices have the same accuracy specifications

The subject and predicate devices are mainly different in that:

- the subject device is single-use device whereas the predicate is reusable; and
- the subject device is intended for patients > 10 kg whereas the predicate is intended for patients >30 kg.

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Substantial Equivalent

Table 12.5 Substantial Equivalent Discussion		
Feature	**Masimo Disposable Forehead Sensor**	**Masimo Reusable Forehead Sensors, LNOP TF-1**
510(k) No.	**Subject Device, Pending**	**Predicate, K032551**
General		
Indications for use	The Masimo Disposable Transflectance Forehead Sensors are indicated for continuous noninvasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate. The Masimo Disposable Transflectance Forehead Sensors are intended for use with adult and pediatric patients, weighing greater than 10 kg, who are well or poorly perfused in healthcare environments.	The following additional Masimo Sensor is indicated for the continuous noninvasive functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate: Reusable oximetry transflectance sensor intended for adults and pediatrics greater than 30 kg in hospitals, hospital-type facilities, mobile, and home environments.
Classification regulation/ product code	Same as K032551	21 CFR 870.2700, Class II / DQA
Principle of operation	Same as K032551	Pulse oximetry is governed by the principles of a) Oxyhemoglobin (oxygentated blood) and b) deoxyhemoglobin (non-oxygenated blood) differ in their absorption of red and infrared light (spectrophotometry). The amount of arterial blood in tissue changes with your pulse (photoplethysymography). Therefore, the amount of light absorbed by the varying quantities of arterial blood changes as well.
Mechanism of actions for achieving the intended use	Same as K032551	The Forehead Sensor is placed on the patient forehead and secured with a headband. The other end of the sensor is connected to a patient cable, which in turn is connected to a pulse oximeter. The instrument is turned on when use begins. Once use is complete, the user turns the instrument power "off" and removes the sensor from the patient.
Patient population	Adults and pediatrics >10 kg	Adults and pediatrics >30 kg
Measurement site	Same as K032551	Forehead
Type of use	Single-use	Reusable
Sterility	Same as K032551	Supplied non-sterile
Compatibility	Instruments with Masimo SET technology provided by Masimo SET or Masimo Rainbow SET technology boards, including the MS, MS-2K and MX series boards	Instruments with Masimo SET technology provided by Masimo SET technology boards, including the MS series boards
Perfusion index (PI)		
PI Function	Same as K032551	PI is the measure of the ratio of the pulsatile blood flow to the non-pulsatile or static blood in peripheral tissue

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Table 12.5 Substantial Equivalent Discussion		
Feature	**Masimo Disposable Forehead Sensor**	**Masimo Reusable Forehead Sensors, LNOP TF-1**
510(k) No.	**Subject Device, Pending**	**Predicate, K032551**
PI Range	Same as K032551	0.02% to 20%
Pleth variability index (PVI)		
PVI Function	Same as K032551	PVI is the measure of dynamic changes in perfusion index that occur during the respiratory cycle. PVI is available based on whether the feature is enabled in the instrument with Masimo SET technology
PVI Range	Same as K032551	0% to 100%
Accuracy, A_{RMS}		
SpO2, no motion	70-100 ± 2 %	70-100 ± 2 %
SpO2, low perfusion	70-100 ± 2 %	70-100 ± 2 %
Pulse rate, no motion	25-240 ± 3 bpm	25-240 ± 3 bpm
Pulse rate, low perfusion	25-240 ± 3 bpm	25-240 ± 3 bpm
Biocompatibility		
Patient-contacting materials	Disposable adhesive sensor with biocompatible patient contact materials:	Reusable sensor with biocompatible patient contact materials:
	Lens: optically clear material for light transmission, polycarbonate	Lens: optically clear material for light transmission, silicon rubber
	Light barrier: polyurethane	Light barrier: PVC
	Sensor face: acrylic adhesive	Sensor face: PVC
	Cable jacket: PVC, medical grade	Cable Jacket: PVC, medical grade

The difference in the indications for use (IFU) between the subject and predicate devices does not raise different questions of safety and effectiveness because both devices have the same intended use as forehead sensors for pulse oximetry, same principle of operation and same accuracy specifications. Although the patient-contacting materials for the subject device and predicate are slightly different, the materials are the same in that they are compliant to ISO-10993-1. Additionally, since the patient population is the same for the subject device and the predicate, there is no expected difference in the subject device's performance with the slight extended weight range for the subject device. Please note the reference device in K051271, where the same patient population of greater than 10 kg does not require additional testing. Furthermore, the subject device has been validated in regards to human factors and usability.

In summary, the accompanied verification and validation data for the subject device, including testing for any differences, demonstrated that the subject device is as safe and effective as the predicate and therefore substantially equivalent to the predicate.

Non-clinical Testing

The subject devices were subjected to bench testing. The following non-clinical testing, as applicable, was performed in accordance with Masimo design control requirements and quality

Section 5. 510(k) Summary

system to demonstrate substantial equivalence of the subject device with its predicates:

- Electrical safety testing per IEC60601-1
- EMC testing per IEC60601-1-2
- Pulse oximetry testing, including simulator testing of pulse rate and low perfusion, per ISO 80601-2-61,
- Biocompatibility testing per ISO-10993-1, ISO-10993-5 and ISO-10993-10
- Usability testing per FDA Human Factors and Usability Guidance
- Software verification per FDA Software Guidance
- Mechanical and environmental testing

Clinical Testing

Clinical performance testing was completed in accordance with ISO 80601-2-61 to evaluate the accuracy of functional oxygen saturation (SpO2) measurements. The Forehead Sensors, connected to MX technology boards with Masimo SET technology, were applied to healthy adult volunteers with light to dark skin pigmentation. SpO2 measurements were compared against arterial blood samples analyzed by a laboratory CO-oximeter, in the range of 70 to 100%, to determine accuracy specifications in terms of accuracy root mean square (Arms). The variation in the accuracy specifications equals plus or minus one standard deviation, which encompassed approximately 68% of the tested population. Arms calculation incorporates error due to bias and imprecision (standard deviation).

Conclusion

The non-clinical and clinical testing provided in this 510(k) submission demonstrates that the subject devices, Forehead Sensors are as safe and effective as the predicate and therefore substantially equivalent to the predicate in K032551.