September 5, 2018

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

Re: K173976
Trade/Device Name: Masimo Acoustic Respiration Sensors
Regulation Number: 21 CFR 870.2700
Regulation Name: Oximeter
Regulatory Class: Class II
Product Code: DQA, BZQ
Dated: August 3, 2018
Received: August 6, 2018

Dear Ms. 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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

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,

James J. Lee -S

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)*
K173976

Device Name
Masimo Acoustic Respiration Sensors

Indications for Use *(Describe)*

The Masimo Acoustic Respiration Sensor RAS-45 Inf/Neo is indicated for continuous, noninvasive monitoring of respiratory rate (RRa®). The Masimo Acoustic Respiration Sensor RAS-45 Inf/Neo is intended for use with infant and neonatal patients, in hospitals, hospital-type facilities, home environments, and transport within healthcare facilities.

The rainbow Acoustic Monitoring® sensors are not indicated for Apnea monitoring.

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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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:	December 27, 2017
Contact:	Sindura Penubarthi Regulatory Affairs Manager
Trade Name:	Masimo Acoustic Respiration Sensors
Common Name:	Pulse Oximeter
Classification Regulation/ Product Code:	21 CFR 870.2700, Class II/DQA – oximeter
Secondary Classification/ Product Code:	Class II/BZQ – breathing frequency monitor
Establishment Registration Number:	2031172
Reason for Premarket Notification:	New Device
Predicate Device:	K120984 – Masimo Acoustic Respiration Sensor (adult/pediatric)
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

The subject device, the Masimo Acoustic Respiration Sensor RAS-45 Inf/Neo, is a noninvasive, disposable, single-use device comprising a piezoelectric sensor element and an adhesive strip that is attached to the patient's chest for the purpose of noninvasive respiration/respiratory rate monitoring in infant and neonatal patients (< 10 kg). Like the predicate (K120984), the RAS-45 Inf/Neo sensor is a rainbow Acoustic Monitoring® sensor intended to be used with, and attached via dual cable to, pulse oximeter monitors incorporating the Masimo rainbow® Acoustic Monitoring technology to provide a continuous calculation and display of the patient's acoustic respiration/respiratory rate (RRa®).

5.2 Intended Use/Indications for Use

The Masimo Acoustic Respiration Sensor RAS-45 Inf/Neo is indicated for continuous, noninvasive monitoring of respiratory rate (RRa®). The Masimo Acoustic Respiration Sensor RAS-45 Inf/Neo is intended for use with infant and neonatal patients, in hospitals, hospital-type facilities, home

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environments, and transport within healthcare facilities.

The rainbow Acoustic Monitoring® sensors are not indicated for Apnea monitoring.

5.3 Device Specifications

Specifications of the RAS-45 Inf/Neo are provided in Table 5.1 below.

Table 5.1 Specifications of RAS-45 Inf/Neo	
Feature	**Specification**
Application Site	Chest
Body Weight	Infant, Neonate < 10 kg
Type of Use	Single-use
Sterility	Supplied non-sterile
Performance	
Respiration Rate Measurement Range	4-120 breaths per minute
Respiration Rate Measurement Accuracy	± 1 breaths per minute, over the entire range
Physical	
General Overall Dimensions	2.18” x 1.7” x 0.12”
Weight	13 grams
Shelf Life	2 years
Patient-Contacting Materials	ISO 10993 compliant
Electrical	
Interface	M6 rainbow® connector
Type of Power	Oximeter dependent
Environmental	
Operating Temperature	+5°C to +40°C, ambient humidity
Storage/Transport Temperature	-40°C to +60°C, ambient humidity
Storage/Transport Humidity	10% to 95%, non-condensing

5.4 Technological Characteristics

5.4.1 Principle of Operation
Rainbow® Acoustic Monitoring involves capture of the acoustic signals (vibrations) associated with respiration via a piezoelectric sensor attached to the measurement site (i.e., patient’s chest). The captured signals are transmitted via the sensor cable and the dual cable to a compatible pulse oximeter monitor where they are digitized and the frequency of the resultant signal envelope (outline) is evaluated to provide and display a real-time, continuous respiratory rate.

5.4.2 Mechanism of Action
The pulse oximeter is turned on for its operation. The RAS-45 Inf/Neo sensor is applied to the patient’s chest. The RAS 45 Inf/Neo sensor and an SpO_2 sensor are connected to a dual channel cable.

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The dual channel cable is connected to a pulse oximeter that has the Masimo rainbow® Acoustic Monitoring technology. The pulse oximeter displays acoustic respiration/respiratory rate (RRa) measurements. Once use is complete, the user turns the pulse oximeter power "off" and removes the sensor from the patient.

5.5 Summary of Similarities and Difference between the Subject and Predicate Devices

The subject device, RAS-45 Inf/Neo, and the predicate device, RAS-125c (K120984), have the following key similarities:

- both have the same intended use,
- both have the same technological characteristics, including principle of operation (except that the subject device intended to be applied to the patient's chest, rather than the neck) and mechanism of action,
- both have the same intended environment (e.g., hospitals, hospital-type facilities, mobile and home environments), and
- both have the same acoustic respiration/respiratory rate (RRa) measurement accuracy (± 1 breaths per minute).

The subject device, RAS-45 Inf/Neo, and the predicate device, RAS-125c, have the following key differences:

- the subject device is designated for use with infant and neonatal patients (< 10 kg) whereas the predicate device is designated for use with adult and pediatric patients (> 10 kg),
- the subject device has a respiration/respiratory rate (RRa) measurement range of 4 to 120 breaths per minute whereas the predicate device has a measurement range of 4 to 70 breaths per minute,
- the subject device is intended to be applied to the patient's chest whereas the predicate device is intended to be applied to the patient's neck, and
- the subject device has a circular shape and a smaller footprint than the predicate device.

Table 5.2 compares specification differences between the RAS-45 Inf/Neo and the RAS-125c.

Table 5.2 RAS-45 Inf/Neo and RAS-125c Comparison

Feature	Specifications	
	RAS-45 Inf/Neo	**RAS-125c**
Application Site	Chest	Neck
Body Weight	Infant, Neonate < 10 kg	Adult, Pediatric > 10 kg
Range and Accuracy, (breaths per minute)	4-120 ± 1, over the entire range	4-70 ± 1, over the entire range
Sensor Shape	Circular	Rectangular

5.6 Non-Clinical Testing

Bench testing was performed on the subject device to validate measurement accuracy (of ± 1 breaths

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per minute) for the entire measurement range of 4 to 120 breaths per minute. Additionally, the following non-clinical testing, as applicable, was performed in accordance with Masimo design control requirements and quality system to demonstrate substantial equivalence of the subject device with its predicate:

- Electromagnetic Compatibility and Electrical Safety testing per IEC 60601-1
- EMC testing per:
  - IEC-60601-1-2
  - ISO 80601-2-61 Clause 202.6.2.3
  - IEC 60601-2-49 Section 202.6.2.101
  - AIM 7351731
- Usability testing per FDA Human Factors and Usability Guidance
- Testing per IEC 60601-1-11
- Biocompatibility testing per ISO-10993
- Mechanical testing per ISTA-2A and MIL-STD 810E
- Environmental testing per IEC-60601-1

5.7 Clinical Testing

Clinical testing was completed to assess clinical performance of the subject device in the infant and neonate population. Production equivalent sensors, connected to pulse oximeters with Masimo rainbow® Acoustic Monitoring technology, were applied to a convenience sample of infant and neonatal patients to gather raw acoustic data. The production equivalent sensors were physically and functionally identical to the RAS-45 Inf/Neo, and only differed in that the sensors did not identify themselves as RAS-45 Inf/Neo sensors to the pulse oximeters. The raw acoustic data was processed through the RAS-45 Inf/Neo algorithm and, as with the predicate K120984, compared against clinicians manually annotating the raw acoustic data. The results showed that the A_{rms} (Accuracy Root Mean Square) of the subject device was 1.1 breaths per minute when compared to the manual/auditory reference method. Clinical performance of the subject device was further assessed by comparison to the performance of a capnography device in a similar infant and neonatal patient population, and the results showed comparable performance (See Table 5.3).

Table 5.3 – Comparison of Clinical Performance of RAS-45 Inf/Neo vs. Capnograph

Device	A_{rms} (breaths per minute)*
RAS-45 Inf/Neo*	1.1
Capnograph*	2.1

*Assessment of clinical performance was based on convenience sampling on two similar cohorts of patients.

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5.8 Conclusion

The information in this 510(k) submission demonstrates that the Masimo Acoustic Respiration Sensor RAS-45 Inf/Neo is substantially equivalent to the predicate device.