May 15, 2020

SonarMed, Inc.
Laura Lyons
VP Compliance & Respiratory Care
12220 N. Meridian St., Ste. 150
Carmel, Indiana 46032

Re: K193058
Trade/Device Name: SonarMed AirWave Airway Monitoring System
Regulation Number: 21 CFR 868.5730
Regulation Name: Tracheal Tube
Regulatory Class: Class II
Product Code: OQU
Dated: April 10, 2020
Received: April 15, 2020

Dear Laura Lyons:

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 ENT, 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

Indications for Use

510(k) 193058
Device Name: SonarMed™ AirWave® Airway Monitoring System

Indications for Use:

The SonarMed AirWave Airway Monitoring System is used to assist in verifying placement of the endotracheal tube (ETT), to assist in detecting movement of the ETT tip, to assist in detecting obstruction of the ETT, and to assist in listening to breath sounds.

The SonarMed AirWave Airway Monitoring System is intended for use by qualified personnel to assist with artificial airway management for patients in an in-hospital setting (intensive care, operating room, and emergency department settings, as well as intra-hospital transport).

The SonarMed AirWave Airway Monitoring System is to be used as an adjunct to normal clinical practice and is a not a stand-alone diagnostic system.

It is intended for use with neonates, infants, children, adolescents, and adults (sizes 2.5 mm to 9.0 mm).

Prescription Use __X_____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)
(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

_____

Concurrence of CDRH, Office of Device Evaluation (ODE)

510(k) Summary
Traditional 510(k) Premarket Notification
SonarMed™ AirWave Airway Monitoring System

K193058

Submitter Information	SonarMed, Inc. 12220 N. Meridian St., Ste. 150, Carmel, IN 46032 317-489-3161 866-853-3684
Contact Person	Laura Lyons Vice President Clinical, Quality & Regulatory 317-489-3161 ext. 208 866-853-3684 (fax)
Date	March 25,2020
Trade Name	SonarMed AirWave Airway Monitoring System
Common Name	Endotracheal Tube Adapter
Classification Name	Airway Monitoring System
Classification Number	21 CFR 868.5730
Product Code	OQU

Predicate Device	SonarMed Airway Management System	K143042	OQU	868.5730

Device Description

The SonarMed AirWave is comprised of a SonarMed Monitor (Monitor) that is used in conjunction with a single-patient use SonarMed Sensor (Sensor) and software that operates the Monitor and Sensor. The Monitor is powered from an external power supply and has a battery backup. When in use, the SonarMed Sensor is placed in-line between the ventilator circuit and the proximal end of the endotracheal tube (ETT) of a patient who is connected to a ventilator.

Using acoustic reflection technology, signals from the Sensor are displayed on the Monitor showing the clinician:

- The baseline location of the ETT tip as established by the clinician
- Estimation of passageway around the tip of the ETT, relative to the ETT diameter
- ETT movement relative to the baseline location
- ETT occlusion / obstruction information including percent obstructed and location of the obstruction
- The clinician can choose whether to view information about the patient's airway in either a waveform or graphic on the Monitor's LCD. Additionally, the clinician can use the microphones to listen to breath sounds. The information provided by the device is to be used in conjunction with normal clinical practice to assist with management of the artificial airway of the patient.

Intended Use

The SonarMed AirWave Airway Monitoring System is used to assist in verifying placement of the endotracheal tube (ETT), to assist in detecting movement of the ETT tip, to assist in detecting obstruction of the ETT, and to assist in listening to breath sounds.

The SonarMed AirWave Airway Monitoring System is intended for use by qualified personnel to assist with artificial airway management for patients in an in-hospital setting (intensive care, operating room, and emergency department settings, as well as intra-hospital transport).

The SonarMed AirWave Airway Monitoring System is to be used as an adjunct to normal clinical practice and is not to be used as a stand-alone diagnostic system.

It is intended for use with neonates, infants, children, adolescents and adults (sizes 2.5 mm – 9.0 mm).

Comparison to Predicate Device

The SonarMed Airway Monitoring System is similar or identical to the predicate in intended use and technology.

Technology

Acoustic reflectometry is used to estimate airway characteristics. The Monitor contains an embedded processor, a graphical display, a user input interface, and a serial communications interface.

Additional sensor sizes have been added to the subject submission. The predicate K143042 included sensor sizes for neonates, infants, younger children, older adolescents and adults. The subject device adds sensor sizes for older children and younger adolescents. These additional sizes are bracketed by the predicate device clearance (K143042).

The sensor has slightly different materials for the speaker gasket and membrane. The new materials are similar in nature as they are medical grade. The predicate device has a silicone elastomer membrane that is attached with a polyurethane medical tape. The subject device has an EVA membrane and uses a polyolefin foam medical tape. Additionally, a silicone sealant is used on the inside and outside. Biocompatibility testing was repeated as a result of the new materials. This testing included gas pathway testing for both polar and non-polar leachables and extractables. Biocompatibility test results demonstrate there are no new safety concerns with the new materials.

Acoustic reflectometry is used to estimate airway characteristics. The Monitor contains an embedded processor, a graphical display, a user input interface, and a serial communications interface.

Additional sensor sizes have been added to the subject submission. The predicate K143042 included sensor sizes for neonates, infants, younger children, older adolescents and adults. The subject device adds sensor sizes for older children and younger adolescents. These additional sizes

are bracketed by the predicate device clearance (K143042).

Modifications were made to the menu options for sound speed correction. The predicate device had two oxygen concentration ranges (21-60 and 61-100), where the subject device has four oxygen concentrations (21-40, 41-60, 61-80, 81-100). Additionally, the auto OR and ICU feature was eliminated, and functionality was added to the waveform screen providing the user with the ability to make changes from that screen. All changes were validated, and the testing confirmed there are no changes to efficacy or safety.

SonarMed Airway Monitoring System	SonarMed Airway Monitoring System	Differences
K193058	K143042	
OQU	OQU	No Differences
868.5730	868.5730	
Technology	**Technology**	
Uses acoustic signals (acoustic reflectometry)	Uses acoustic signals (acoustic reflectometry	No Differences
Has 2 microphones and 1 speaker	Has 2 microphones and 1 speaker	No Differences
Uses acoustic reflections to estimate airway characteristics	Uses acoustic reflections to estimate airway characteristics	No Differences
Uses analysis software to present data in graphical manner	Uses analysis software to present data in graphical manner	No Differences
Indications for Use	**Indications for Use**	
Verifies ETT placement	Verifies ETT placement	No Differences
Detects movement of the endotracheal tube and displays on monitor	Detects movement of the endotracheal tube and displays on monitor	No Differences
Provides real-time continuous monitoring of the airway	Provides real-time continuous monitoring of the airway	No Differences
Detects obstructions/occlusions in the airway	Detects obstructions/occlusions in the airway	No Differences
Estimates the diameter of the anatomical structure around the tip of the ETT	Estimates the diameter of the anatomical structure around the tip of the ETT	No Differences
Uses microphones for listening to breath sounds	Uses microphones for listening to breath sounds	No Differences

Population & Sensor Sizes	**Population & Sensor Sizes**	
• Sizes 2.5 mm – 9.0 mm	• Sizes 2.5, 3.0, 3.5 and 6.5-9.0 mm	Additional Sensor Sizes 4.0 to 6.0 mm

• Neonates, infants, children, adolescents, and adults	• Neonates, infants, younger children, older adolescents, and adults	Added sizes for older children and younger adolescents
• Sensor weight 0.5 oz (14g) (neonates, infants, children)	• Sensor weight 0.5 oz (14g) (neonates, infants)	No Differences
• Weight 0.9 oz (28g) (adolescents and adults)	• Weight 0.9 oz (28g) (adolescents and adults)	No Differences
Performance	**Performance**	
• Bench testing for verifying placement, detecting movement, detecting obstructions	• Bench testing for verifying placement, detecting movement, detecting obstructions	As accurate or more accurate than predicate
Materials	**Materials**	
• Monitor	• Monitor	No Differences
• Sensor: Polypropylene, Silicone Elastomer, Polycarbonate, Polyurethane Medical Tape	• Sensor: Polypropylene, Silicone Elastomer, Polycarbonate, EVA Membrane, Polyethylene Tape, Polyolefin Foam Medical Tape	New Materials in Subject Device are: EVA Membrane, Polyethylene Tape, Polyolefin Foam Medical Tape In predicate but not contained in subject device: Polyurethane Medical Tape
Electronic Components	**Electronic Components**	
• Printed Circuit Boards (populated components)	• Printed Circuit (populated components)	Populated components on the Subject device were updated to address obsolescence, however all functionality remained the same.
Software	**Software**	
• Alarms	• Alarms	Updated to meet IEC 60601-1-8 (Alarm Standard)
• O_2 Ranges 21-60% and 61-100%	• O_2 Ranges 21-40%, 41-60%, 61-80%, 81-100%	Four ranges are now provided across all patient populations
• Auto OR and Auto ICU in Menu	• Functionality on Waveform Screen	Functionality added to Waveform Screen

Discussion and Conclusion of Non-Clinical Testing

Several different bench tests were completed to demonstrate substantial equivalence. The bench testing compared movement, obstruction and passageway accuracy of the subject device. (Subject device patient populations: neonate, infant, child, adolescent and adult) to the predicate, K103042 (Predicate device: neonate, infant, younger child, older adolescent and adult).

The Passageway Detection Study documented that the subject device accurately estimates the diameter of the passageway around the tip of the ETT for all patient populations.

The Movement Study documented that the subject device accurately detects the distance and direction of the ETT tip movement both upward and downward for all patient populations.

The Obstruction Detection Study documented that the subject device accurately detects the percentage of obstruction in the ETT for all patient populations.

Additionally, the subject device was tested for:

- Medical electrical equipment following IEC 60601-1:2015; Edition 3.1
- Basic Safety and Essential Performance, following IEC 60601-1-2
- General requirements tests and guidance for alarm system in medical environment, following IEC 60601-1-8, Edition 2.1 2012-11
- Biological evaluation of medical devices-Part 5: Tests for in vitro cytotoxicity, following ISO 100993-5, Third edition 2009-06-01
- Biological evaluation of medical devices-Part 10: Tests for irritation and skin sensitization, following ISO 10993-10 Third Edited 2010-08-01
- Biocompatibility evaluation of breathing gas pathways in healthcare applications, following ISO 18562 First Edited 2017-03
- Medical device software, following IEC 62304, Edited 1.1 2015-06

All testing passed.

SonarMed performed an exhaustive extraction at 50°C for 72 hours on the final finished device using polar and non-polar solvents per ISO 10993-12. A toxicological risk assessment was conducted on the compounds that were identified in the extractable and leachable testing. The risk assessment did not identify any additional question of safety, including that the identified compounds raised no genotoxicity or carcinogenicity concerns.

Conclusion: Based on the comparison of technological characteristics and non-clinical testing summarized in this 510(k) submission, the results demonstrate that the subject device is substantially equivalent to the predicate. The differences do not raise different questions of safety or effectiveness when compared to the predicate.