DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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Silver Spring, MD 20993-0002

January 22, 2016

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

Re: K143042
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: January 13, 2016
Received: January 19, 2016

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. 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,

Tejashri Purohit-Sheth, M.D.

Tejashri Purohit-Sheth, M.D.
Clinical Deputy Director
DAGRID/ODE/CDRH FOR

Erin I. Keith, M.S.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and Radiologic Health

Enclosure

Indications for Use

510(k) Number: K143042

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 not to be used as a stand-alone diagnostic system.

It is intended for use with patients who use ET tube sizes 2.5, 3.0, 3.5, and for sizes 6.5, 7.0, 7.5, 8.0, 8.5, and 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 Summary
SonarMed™ AirWave Airway Monitoring System

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 Compliance & Respiratory Care 317-489-3161 ext. 208 866-853-3684 (fax)
Date	October 16, 2014
Trade Name	SonarMed AirWave Airway Monitoring System
Common Name	Endotracheal Tube Adapter
Product Code	OQU
Classification Name	Tracheal Tube
Classification Number	21 CFR 868.5730

Predicate Device	SonarMed Airway Management System	K092611	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
- Quantification of diameter of the anatomical structure around the tip of the ETT
- 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. This information should only be used in an adjunctive manner to assist with management of the artificial airway of the patient.

The monitor allows the user to manually adjust the sound of speed. This is to compensate for the changes in the sound of speed with high oxygen concentrations and the use of anesthesia gases. The monitor also has an auto-speed of sound mode. This mode automatically changes the speed of sound.

The monitor allows the user to manually enter the distance to the carina from the chest x-ray. This is an optional feature that the user can elect from the setting menu. Once selected the algorithm will calculate the distance to the carina based on the movement of the tip of the tube.

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 patients who use ET tube sizes 2.5, 3.0, 3.5, and for sizes 6.5, 7.0, 7.5, 8.0, 8.5, and 9.0 mm.

Comparison to Predicate Devices

The SonarMed Airway Monitoring System is similar or identical to the predicate in indications for use and technology. The differences to the predicate is the addition of two new features in the subject device; the user can input the distance from the tip of the tube to the carina as determined by the chest x-ray, and sound of speed mode, which allows for both manual and automatic corrections to the sound of speed in high levels of oxygen and anesthesia gases. Also the subject device has a biocompatible silicone tube over the microphones.

Technological Characteristics

The SonarMed AirWave uses the exact same technology as the predicate device. The SonarMed AirWave consists of two components: a plastic disposable ET tube Sensor and a portable digital Monitor. The SonarMed Sensor contains a speaker, two microphones, and a cable.

The SonarMed AirWave Sensor is manufactured with the same plastics as the predicate. The outer body is Polycarbonate; the nozzle is Polypropylene. The internal lumen is also Polycarbonate, and also contains Silicone (which is a new material added to make the sensor more mucus resistant).

The speaker and microphones acoustically communicate with the tube lumen. The cable connects the speaker and microphones to a portable digital Monitor. The Monitor contains an embedded processor, a graphical display, a user input interface, and a serial communications interface.

The predicate device, the SonarMed Airway Monitoring System, uses the exact same technology. There is no difference in the technological characteristics from the predicate to the new device. There are new features in the subject device (Distance to Carina and Speed of Sound Modes).

SonarMed AirWave (K143042) New device	**SonarMed Airway Monitoring System (K092611) Predicate**
Uses speaker and two microphones	Uses speaker and two microphones
Reusable monitor	Reusable monitor
Embedded processor, a graphical display, a user input interface, and a serial communications interface	Embedded processor, a graphical display, a user input interface, and a serial communications interface
Plastic single patient use sensor	Plastic single patient use sensor
Cable attaches sensor to monitor	Cable attaches sensor to monitor
Sensor Materials: Polycarbonate, Polypropylene, Silicone	Sensor materials: Polycarbonate, Polypropylene
Optional Distance to Carina feature	Not included
Speed of Sound Modes	Not included
For use with ETT sizes 2.5, 3.0, 3.5 and 6.5-9.0 mm	For use with ETT sizes 6.5-9.0 mm
Size (for 2.5, 3.0 and 3.5 mm ETTs) 1.375” x 0.688” x 1” / 3.5 x 1.7 x 2.5 cm Size (for 6.5-9.0 mm ETTs) 2.125” x 1.125” x 1.125” / 5.4 x 2.9 x 2.9 cm	Size 2.125” x 1.125” x 1.125” / 5.4 x 2.9 x 2.9 cm
Weight 14 g (for 2.5, 3.0 and 3.5 mm ETTs) Weight 28 g (for 6.5-9.0 mm ETTs)	Weight 28 g
Dead space 0.5 ml (for 2.5, 3.0 and 3.5 mm ETTs) Dead space 3.0 ml (for 6.5-9.0 mm ETTs)	Dead space 3.0 ml

Discussion and Conclusion of Non-Clinical Testing

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. The site of exposure is the humidified gas pathway of the patient. SonarMed performed testing for cytotoxicity, sensitization and intracutaneous reactivity, which all passed. Also an exhaustive E&L testing was performed. All of the reported extractable and leachable compounds have been determined to be present at levels well below that which would have any health consequences to the intended neonatal population and large safety margins (very large in many cases) have been determined from the risk characterizations process.

Both bench testing and animal testing was completed for the non-clinical testing for determination of substantial equivalence.

Several bench tests were performed. One test compared movement and passageway accuracy of the infant sized sensor to the predicate, adult sized sensor. Another test compared the obstruction accuracy of the infant sized sensor to the predicate, adult sized sensor. All testing passed.

A long-term bench study was conducted to document that the subject device performs as intended during prolonged use with heated, humidified, positive pressure ventilation. The conclusion of the bench study was that the SonarMed AirWave Sensor functions as intended during prolonged use for over 30 days.

The pre-clinical study was designed to verify the acoustics in the smaller airways would allow for very precise tracking of tube movement and tube location. The study utilized an animal model (rabbit) that was known to be close to the human neonatal airways. During the study, the endotracheal tube was moved up and down in the trachea, into the bronchus and also into the esophagus. These movements were made in small increments and tracked with the SonarMed monitor.

The pre-clinical study concluded that the tracking algorithm is accurate in determining ETT tip movement and passageway size.

The conclusions drawn from the non-clinical testing are that the new, infant sized sensors are at least as accurate as the predicate, adult size sensors in detecting movement, obstruction and passageway size and that they function as intended during prolonged use.

Clinical data and conclusions were not needed for this device.

Conclusion

The SonarMed AirWave was modified to be small enough for the neonatal/pediatric endotracheal tubes. The sensor was designed to be as small as possible with minimal dead space. The new, infant sized sensors are at least as accurate as the predicate, adult size sensors in detecting movement, obstruction and passageway size, and they function as

intended during prolonged use.

The conclusions drawn from the nonclinical testing demonstrate that the device is as safe, as effective, and performs as well as the predicate device.