K092611

SonarMed™ Airway Monitoring System

510(k) Summary
Traditional 510(k) Premarket Notification
Summary of Safety and Effectiveness

APR 29 2010

Submitter Information	SonarMed, Inc. 5513 West 74th St, Indianapolis, IN 46268 317-489-3161 866-853-3684
Contact Person	Laura Lyons Vice President Clinical, Quality & Regulatory Affairs 317-489-3161 ext. 208 866-853-3684 (fax)
Date	August 24, 2009
Trade Name	SonarMed™ Airway Monitoring System
Common Name	Airway Monitoring System
Product Code	OQU
Classification Number	21 CFR 868.5730

Predicate Devices

Eccovision Acoustic Diagnostic Imaging Pharyngometer	K011329	BXQ	868.1800
ETView Tracheoscopic Ventilation Tube	K082420	BTR	868.5730
PosiTube Esophageal Intubation Detection	K000045	BTR	868.5730
RhinoScan Acoustic Rhinometry	K000406	BXQ	868.1800
Tidal Wave SP Model 710/715	K032971	DQA	870.2700

Device Description

The SonarMed AMS is comprised of a SonarMed Monitor (Monitor) that is used in conjunction with a sterile, single-use SonarMed Adapter (Adapter) and software that operates the Monitor and Adapter. The Monitor is powered from an external power supply and has a battery backup. When in use, the SonarMed Adapter is placed in-line between the ventilator circuit and the

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proximal end of the endotracheal tube (ETT) of a patient who is connected to a ventilator.

Using sonic reflection technology, signals from the Adapter allow the color LCD on the Monitor to display to a clinician:

- The baseline location of the ETT tip as established by the clinician
- Quantification of passageway diameter relative to the ETT diameter (for example a reading of less than 1 may indicate the tube is in a passageway that is smaller than itself, such as the esophagus)
- ETT movement relative to the baseline location
- ETT occlusion / obstruction information including percent obstructed

The clinician can choose whether to view information about the patient's airway in either a waveform or graphic on the Monitor's color LCD. This information should only be used in an adjunctive manner to assist with management of the artificial airway of the patient.

Intended Use

The SonarMed AMS is intended to be used to assist in verifying placement of the ETT, to assist in detecting movement of the ETT tip, and to assist in detecting obstruction of the ETT.

The SonarMed AMS 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 AMS 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 from 6.5 mm to 9.0 mm weighing >35 kilograms.

Comparison to Predicate Devices

The SonarMed Airway Monitoring System is similar or identical in technology, intended use, performance and environments of use.

Technological Characteristics

The SonarMed AMS consists of two components: a plastic disposable ET tube Adapter and a portable digital Monitor. The SonarMed AMS Adapter contains a speaker, two microphones, and a cable. The speaker and microphones, which acoustically communicate with the tube lumen via ports, have electrical connections running to the cable exiting the Adapter. 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. Both the Eccovision Acoustic Diagnostic Imaging Pharyngometer and the RhinoScan Acoustic Rhinometry use the same technology.

The Tidal Wave SP, ETView Tracheoscopic Ventilation Tube and the PosiTube Esophageal Intubation Detection verify placement within the airway. The Tidal Wave SP and the ETView Tracheoscopic Ventilation Tube detect movement of the endotracheal tube. The Acoustic Diagnostic Imaging Pharyngometer and the Tidal Wave SP detect obstruction in the airway.

Performance

The results of non-clinical (lab) performance testing demonstrate that the device

of Non-Clinical is safe and effective.

Clinical data and conclusions were not needed for this device.

End of document.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

APR 29 2010

Ms. Laura Lyons
Vice President, Clinical, Quality & Regulatory Affairs
SonarMed, Incorporated
5513 West 74th Street
Indianapolis, Indiana 46268

Re: K092611
Trade/Device Name: SonarMed™ Airway Monitoring System
Regulation Number: 21 CFR 868.5730
Regulation Name: Tracheal Tube
Regulatory Class: II
Product Code: OQU
Dated: April 27, 2010
Received: April 28, 2010

Dear Ms. 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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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 Small Manufacturers, International and Consumer Assistance 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,

for

Anthony Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number:

Device Name: SonarMed™ Airway Monitoring System

Indications For Use:

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The SonarMed AMS 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).

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L Schultheiss

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K092611

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)