K062020

Non-Confidential Summary of Safety and Effectiveness
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29-Aug-06

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SEP - 5 2006

Official Contact: Peter Derrico - President

Proprietary or Trade Name: Lifesound esophageal stethoscope and temperature sensor

Common/Usual Name: Stethoscope, Esophageal with electrical conductors

Classification Name: Stethoscope, Esophageal with electrical connectors

Device: Lifesound esophageal stethoscope

Predicate Devices: Biomedical Concepts (NovaMed) – K864858
Shore Medical – K982193

Device Description:

The NovaMed esophageal stethoscopes are long tubes which at the distal end have openings in the side wall and tip end. These openings are covered by a thin non-inflatable cuff to prevent secretions from entering in the distal end.

A temperature sensor or electrical conductor can be placed inside the distal end with connecting wires running internally and exiting the proximal end of the stethoscope. The proximal end is fitted with a standard slip fit luer for connection to any standard earpiece or to the Lifesound electronic stethoscope (K844804). The insulated temperature sensor wires are terminated with standard connectors for fitting to standard cables which connect to the temperature monitor. They are available is various lengths, diameters (sizes), with or without temperature, and packaged clean, non-sterile and sterile.

Indications for Use:

Indicated Use -- For use as an esophageal stethoscope to listen to patient heart and breathe sounds while a patient is under anesthesia or sedation.

Optionally it may be used as a temperature sensor to monitor patient temperature.

The electrical conductors are YSI 400 or 700 series compatible.

They can be provided "clean, non-sterile" or "sterile".

Environment of Use -- Hospital, sub-acute care or any setting requiring the monitoring of breath sounds and / or temperature

Device Attributes:

	NovaMed Esophageal Stethoscope
Attributes	
Intended use General	Monitor heart and breathe sounds Optional configuration to monitor temperature
Intended use Specific	Esophageal stethoscope Monitor patient temperature For patients under anesthesia or sedation.
Environments of use	Hospital, sub-acute care or any settings where monitoring of breathe sounds and /or temperature is required
Prescription	Yes
Design	
	Inner tube with holes at distal end, covered with non-inflating cuff with proximal end terminating in a luer fitting. Electrical conductor / temperature sensor which connects to standard monitors YSI 400 or 700 series compatible.
Materials	
Components in air pathway	PVC
Performance	
	None applicable

Differences between Other Legally Marketed Predicate Devices

The NovaMed esophageal stethoscope is viewed as substantially equivalent to the following predicate devices – Biomedical Concepts (NovaMed) esophageal stethoscope – K864858 and Shore Medical – K982193.

There are no significant differences that affect the safety or effectiveness of the intended device as compared to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP - 5 2006

NovaMed, LLC
C/O Mr. Paul Dryden
President
ProMedic, Incorporated
3460 Pointe Creek Court, #102
Bonita Springs, Florida 34134-2015

Re: K062020
Trade/Device Name: Lifesound Esophageal Stethoscope and Temperature Sensor
Regulation Number: 21 CFR 868.1920
Regulation Name: Esophageal Stethoscope with Electrical conductors
Regulatory Class: II
Product Code: BZT
Dated: July 14, 2006
Received: July 17, 2006

Dear Mr. Dryden:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D.
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 Statement

510(k) Number: **K062020** (To be assigned)

Device Name:

Lifesound Esophageal Stethoscope and Temperature Sensor

Indications for Use:

Indicated for use as an esophageal stethoscope to listen to patient heart and breathe sounds while a patient is under anesthesia or sedation.

Optionally it may be used as a temperature sensor to monitor patient temperature.

The electrical conductors are YSI 400 or 700 series compatible.

They can be provided "clean, non-sterile" or "sterile".

Prescription Use XX (Part 21 CFR 801 Subpart D) **or** **Over-the-counter use __** (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Sign-Off)
sion of Anesthesiology, General Hospital,
ction Control, Dental Devices

) Number: K062020