K103516

FEB - 4 2011

5 510(k) Summary

Summary of Safety and Effectiveness

As required by 21 CFR, part 807.92

Submitted By: Inovise Medical, Inc.
8770 SW Nimbus Avenue
Suite D
Beaverton, OR 97008-7196
Phone: (503) 431-3800
Toll Free: (877) 466-8473
Fax: (503) 431-3801

Contact: Earl Anderson
Director, Quality and Regulatory

Date Prepared: November 19, 2010

Proprietary Name: AUDICOR™ Sensor 4.0 with Adapter (Modification to AUDICOR™ Sensor 2.0 with Adapter)

Common/ Usual Name: ECG/ Heart Sound Sensor

Classification: 870.2360, DRX, class II, Electrocardiograph electrode
870.1875, DQD, class II, Stethoscope, electronic

Performance Standards: ANSI/AAMI EC12:2000

Intended Use: The Audicor® Sensors with Adapters are a family of dual-function transducers for use on patients where combined ECG/heart sounds data are needed for the evaluation of patient status, to aid in diagnosis and determine effects of treatment on ECG and hemodynamics. Audicor Sensors with Adapters may be used only with a compatible Audicor System.

There are disposable and reusable versions of the Audicor Sensor. Both can be used in the recording of resting ECG / heart sound reports. The disposable Audicor Sensor is also intended for longer term monitoring applications of up to 48 hours.

Device Description: The Audicor Sensors with Adapters are a group of devices that are intended for use with Audicor-enabled ECG/heart sounds detections systems. Sensors are designed with conductive patient-contact surfaces to enable capture of ECG data. The mating cable adapter for Sensor 4.0 includes an accelerometer for detection of heart sounds. The sensor and adapter devices are intended for use on the chest wall in the V3 and V4 positions.

Audicor sensors are available in two versions:

1) Single-use disposable sensors, for use up to 48 hours (Sensor 2.0 and Sensor 4.0)
2) Reusable sensors (Sensor 3.0)

Predicate Device: AUDICOR™ 2.0 Sensor -510(k) K080602

Test Summary & Conclusion: The Audicor sensors have been tested to the applicable requirements of the following standards, and shown to comply.

- ANSI/AAMI EC12:2000 – Disposable ECG Electrodes
- ISO 10993-1:2009, Biological Evaluation of Medical Devices – Evaluation and testing.

Substantial Equivalence: The Audicor Sensors are substantially equivalent to the Audicor™ Sensor 2.0 (K080602). Modifications include:

- Replacement of the sensor microphone transducer with an accelerometer transducer
- Heart sound transducer function moved from the disposable sensor to the mating cable adapter head.

Technological Characteristics:

- The Audicor sensors/adapters included in this submission are technologically equivalent to the predicate in that both are dual function sensors (ECG/heart sounds detection) and are designed for use with Audicor-enabled ECG/heart sounds systems.

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

Inovise Medical, Inc.
c/o Mr. Earl Anderson
Quality and Regulatory Director
8770 SW Nimbus Avenue, Suite D
Beaverton, OR 97008-7196

FEB - 4 2011

Re: K103516
Trade/Device Name: AUDICOR™ Sensor 4.0 with Adapter
Regulation Number: 21 CFR 870.1875
Regulation Name: Electronic Stethoscope
Regulatory Class: Class II (two)
Product Code: DQD, DRX
Dated: November 19, 2010
Received: November 30, 2010

Dear Mr. Anderson:

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.

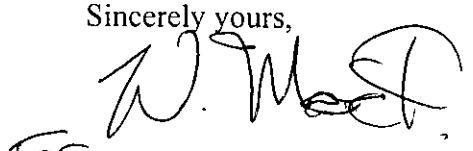
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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 Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

4 Indications for Use Statement

510(k) Number (if known): K103516

Device Name: AUDICOR™ Sensor 4.0 with Adapter

Indications For Use:

The Audicor™ Sensors with Adapters are a family of dual-function transducers for use on patients where combined ECG/heart sounds data are needed for the evaluation of patient status, to aid in diagnosis and determine effects of treatment on ECG and hemodynamics. Audicor Sensors with Adapters may be used only with a compatible Audicor System.

There are disposable and reusable versions of the Audicor Sensor component. Both can be used in the recording of resting ECG / heart sound reports. The disposable Audicor Sensor is also intended for longer term monitoring applications of up to 48 hours.

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)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K103516