SEP 09 2008

Summary of Safety and Effectiveness

As required by 21 CFR, part 807.92

Submitted By: Inovise Medical, Inc.
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Contact: Kendra Rathkey
Manager, Quality and Regulatory

Date Prepared: July 2, 2008

Proprietary Name: Modification to AUDICOR 200

Common/ Usual Name: Electrocardiograph/Acoustic Cardiograph

Classification: 870.2340, DPS class II, Electrocardiograph
870.1875, DQD, class II, Electronic Stethoscope
870.2800, MLO, class II, Electrocardiograph, Ambulatory (with analysis program)

Performance Standards: AAMI EC 11

Intended Use: The Audicor® System, when used with AUDICOR Sensors on the chest wall, is intended for use in acquiring, analyzing and reporting ECG and heart sound data and to provide interpretation of the data in an integrated ACG (acoustic cardiograph) report for consideration by physicians. Audicor systems allow detection, reporting and interpretation of standard ECG data as well as advanced parameters such as EMAT, LVST, S3 strength, S4 strength, and SDI.

Data may be reported in a single snapshot report and in a trended report format where multiple data points are trended over time. The Audicor system also accepts and analyzes downloads of up to 48 hours of patient data from an optional ambulatory ECG/heart sounds collection device.

ECG and heart sound data offered by the device are only significant when used in conjunction with physician over read as well as consideration of other relevant patient data.

The device is intended for use only under the direct supervision of a physician and is for use on adults (≥ 18 years).

Device Description: The Audicor 200 is a stand-alone device that can be used to capture 10-second snapshots of ECG and heart sounds in patients suspected of heart failure or acute coronary syndrome.

The Audicor TS system, a combination of the Audicor 200 with an Audicor-enabled laptop computer, is used to display and analyze patient data over time in a trended format. The trending system can be used in monitoring patient changes during therapeutic treatment or during CRT studies.

The Audicor system, when used with either a 10 wire or 4 wire patient cable analyzes and reports the following advanced parameters and a systolic dysfunction index (SDI) calculated from advanced parameters:

- LVST (Left Ventricular Systolic Time)
- LVDT (Left Ventricular Diastolic Time)

- PADT (Pre-atrial Diastolic Filling Time)
- AAFT (Accelerated Atrial Filling Time)
- EMAT (QS1, Electromechanical Activation Time)
- QS2
- R-R Interval
- S3 Strength
- S4 Strenth
- SDI (Systolic Dysfunction Index)

The Audicor-enabled laptop computer also accepts, analyzes and displays trended data from an optional ambulatory data collection harness for trend and event analysis.

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

- ANSI/AAMI EC-11 Standard for Diagnostic Electrocardiographic Devices
- EN 60601-1 (UL 60601-1) Standard for Medical Electrical Equipment: General Requirements for Safety
- EN 60601-1-2 Standard for Medical Electrical Equipment Part 1-2: General Requirements for Safety – Collateral Standard: Electromagnetic Compatibility – Requirements and Tests
- IEC 60601-2-25 Medical Electrical Equipment Part 2-25: Particular Requirements for the Safety of Electrocardiographs
- IEC 606601-2-51 Medical Electrical Equipment Part 2. Particular Requirements for Safety, Including Essential Performance, of Recording and Analyzing Single Channel and Multi-channel Electrocardiographs

The optional ambulatory ECG/heart sounds data collection harness (Hemo) is designed to comply with

- ANSI/AAMI EC38:1998 Ambulatory Electrocardiographs

Substantial Equivalence: The added Hemo accessory wireless ambulatory ECG/heart sounds data collection harness is found to be substantially equivalent to the following cleared devices:

- GE Medical Systems SEER Light Holter Recorder (K021470)

Technological Characteristics: The Audicor System Hemo wireless ECG/heart sounds data collection harness and the predicate GE SEER Light Holter Recorder are technologically equivalent in that both devices:

- Are small, wearable, battery-powered devices
- Acquire ECG data from patients using limited ECG leads
- Use non-volatile memory to store patient data for download to the analysis module of the system

The Audicor Ambulatory system is different from the predicate in the following ways:

- It requires use of proprietary Audicor sensors to capture ECG and heart sounds data
- The GE SEER Light does not perform the analysis on recorded data while the Audicor system does.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Inovise Medical, Inc.
c/o Ms. Kendra Rathkey
Manager, Quality and Regulatory
10565 SW Nimbus Avenue
Suite 100
Portland, OR 97223-4311

Re: K073545
Trade Name: AUDICOR Hemo Ambulatory Monitor
Regulation Number: 21 CFR 870.2800
Regulation Name: Medical Magnetic Tape Recorder
Regulatory Class: Class II (two)
Product Code: MWJ
Dated: August 6, 2008
Received: August 11, 2008

Dear Ms. Rathkey:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we 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). 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 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 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html

If you have any questions regarding the content of this letter, please contact Frank Lacy at (240) 276-4095.

Sincerely yours,

Donna R. Bachman

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K073545

Indications for Use

510(k) Number (if known): K073545

Device Name: AUDICOR Hemo Ambulatory Monitor

Indications For Use:

The Audicor® System, when used with AUDICOR Sensors on the chest wall, is intended for use in acquiring, analyzing and reporting ECG and heart sound data and to provide interpretation of the data in an integrated ACG (acoustic cardiograph) report for consideration by physicians. Audicor systems allow detection, reporting and interpretation of standard ECG data as well as advanced parameters such as EMAT, LVST, S3 strength, S4 strength, and SDI.

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Prescription Use __XXX_____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (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)

Donna R. Lechner

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K073545