K110569
p1/3

OCT 24 2011

Summary of Safety and Effectiveness

As required by 21 CFR, part 807.92

Submitted By:	Inovise Medical, Inc. 8770 SW Nimbus Ave, Suite D Beaverton, OR 97008-7196 Phone 503-313-0149 Fax 503-431-3801
Contact:	Earl Anderson Director, Quality and Regulatory
Date Prepared:	September 30, 2011
Proprietary Name:	AUDICOR CPAM (Cardiopulmonary Ambulatory Monitor)
Common/ Usual Name:	Ambulatory Monitor / Acoustic Cardiograph
Classification:	870.2800, MLO, class II, Electrocardiograph, Ambulatory (with analysis program)
Performance Standards:	ANSI/AAMI EC38 and ANSI/AAMI EC57
Intended Use:	The Audicor® System, when used with AUDICOR Sensors on the chest wall and properly attached Holter unit, is intended for use on adults 18 years of age and older in acquiring, analyzing and reporting ECG and heart sound data and to provide interpretation of the data in an integrated report for consideration by physicians. The Audicor recording may be obtained at any location specified by a physician including home, hospital or clinic. The measurements provided and interpretations of 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.
Device Description:	The Audicor System is an ambulatory device that can be used to capture up to 48 hours of continuous data or 10-second snapshots of ECG and heart sounds data. The Audicor System includes software to display, analyze and provide a summary of patient data over time in a trended format. Notable events are detected and displayed for review by the clinician. The analysis package includes heart rate variability and performs ECG beat classification, editing and reporting of arrhythmias. The Audicor System analyzes and reports the following parameters: • Heart sound and combined ECG/heart sound measurements

<table>
<tr><td></td><td>
• Heart rate distributions of heart sound parameters
• Heart rate and associated events
• Atrial fibrillation
• ECG beat classification and morphology grouping
• Ventricular and atrial ectopic beat arrhythmias
• Heart rate variability
</td></tr>
<tr><td>Test Summary & Conclusion:</td><td>
The Audicor System has been tested to the applicable requirements of the following standards, and shown to comply.
• EN 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
• ANSI/AAMI EC38:Ambulatory Electrocardiographs
• ANSI/AAMI EC57: Test and Reporting Performance Results of Cardiac Rhythm and ST-segment Measurement Algorithms
• Compliance to internal Inovise Medical software and algorithm performance assessment protocols
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<tr><td>Substantial Equivalence:</td><td>
The functionality for reporting of ECG and heart sound analysis including heart rate variability and Holter ECG features (beat classification, editing and reporting of arrhythmias) are substantially equivalent to:

<table>
<tr><th>Product Functionality</th><th>Predicate</th></tr>
<tr><td>ECG and Heart Sound Recording and Analysis</td><td>Audicor Hemo Ambulatory Monitor (510(k) K073545);
Spacelabs Pathfinder SL (510(k) K110001)</td></tr>
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<tr><td>Technological Characteristics:</td><td>
The Audicor System and the predicate devices (Spacelabs Pathfinder SL and Audicor [Hemo] AM) are technologically equivalent in that the devices:

• Are small, wearable, battery-powered devices
• Acquire ECG data from patients using limited ECG leads, as well as perform beat classification, editing, reporting of arrhythmias and heart rate variability
• Use non-volatile memory to store patient data for further analysis

Substantial equivalence has been measured by review of the respective technologies and their effectiveness to provide equivalent performance.

The technological characteristics of the AUDICOR system compares to the
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</table>

predicates as follows:

Product Functionality	Predicate	Comparison
ECG and Heart Sound Recording; Heart Sound Analysis	Audicor Hemo Ambulatory Monitor (510(k) K073545)	Same platform and specification for ECG and heart sound acquisition and analysis as predicate.
Heart Rate Variability and ECG Holter analysis and report generation (beat classification, edting and reporting of arrhythmias)	Pathfinder SL, Spacelabs (510(k) K110001)	Both are Windows-based ECG analysis systems, editing and report generation systems that include heart rate variability.

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

OCT 24 2011

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

Re: K110569
Trade/Device Name: Audicor System
Regulatory Number: 21 CFR 870.2800
Regulation Name: Ambulatory Electrocardiograph with Analysis Algorithm
Regulatory Class: II (two)
Product Code: 74 MLO
Dated: September 30, 2011
Received: October 11, 2011

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.

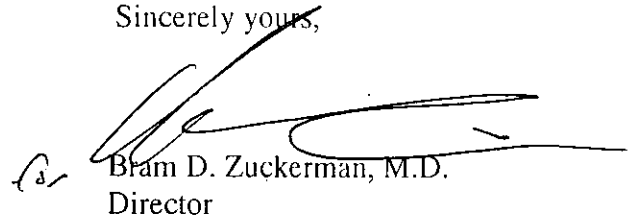
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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,



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

Enclosure

Indications for Use

510(k) Number K110569

Device Name: Audicor System

Indications For Use:

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The measurements provided and interpretations of 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.

Prescription Use __XXX_____ 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 K110569