K070136

Summary of Safety and Effectiveness

As required by 21 CFR, part 807.92

APR 13 2007

Submitted By:	Inovise Medical, Inc. 10565 SW Nimbus Ave, Suite 100 Portland, OR 97233-4311 Phone 503-431-3837 Fax 503-431-3801
Contact:	Steve Hesler Director, Quality and Regulatory
Date Prepared:	January 15, 2007
Proprietary Name:	SDI Modification to AUDICOR 200 System
Common/ Usual Name:	Electrocardiograph/Acoustic Cardiograph
Classification:	870.2340, DPS class II, Electrocardiograph 870.1875, DQD, class II, Electronic Stethoscope
Performance Standards:	AAMI EC 11
Intended Use:	The Audicor 200 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 report for consideration by physicians. In addition the Audicor 200 System can be used with an add-on laptop computer that allows data to be presented in the format of real-time and trended display of cardiac indices derived from simultaneous ECG data and heart sounds data. The 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, 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 evaluations of ECG and heart sounds in patients suspected of heart failure or acute coronary syndrome. In addition the system can be connected to a compatible laptop computer and 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.
Test Summary & Conclusion:	The Audicor 200 System has been tested to the applicable requirements of the following standards, and shown to comply. • 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

- AAMI EC 11 Diagnostic Electrocardiographic Devices

Substantial Equivalence: The Inovise Audicor 200 System with added interpretive statements is substantially equivalent to the AUDICOR® 200 system (K043074, cleared as Liberty) with the incorporation of Audicor Advanced Parameters (K051450, cleared as Extended Measurements)

Technological Characteristics: The SDI modification to the Audicor 200 System and the AUDICOR 200 predicate device are technologically equivalent in that both acquire ECG and heart sounds data from adult patients then present the data in the AUDICOR report format which can include graphic display of MI and LVH conditions along with detection and display of S3 and S4 heart sounds. Both systems can analyze and display "Advanced Parameters" derived from ECG and heart sounds information to include:

- Left Ventricular Systolic Time (LVST)
- Left Ventricular Diastolic Time (LVDT)
- Pre-atrial Diastolic Filling Time (PADT)
- Accelerated Atrial Filling Time (AAFT)
- QS1 (EMAT)
- QS2
- R-R Interval
- S3 Strength
- S4 Strength
- S1/S2 Intensity Ratio

The SDI modification to the Audicor 200 System includes addition of a new parameter, the Systolic Dysfunction Index (SDI). The system will also display added interpretive statements when analysis of patient data warrants. The added statements, appropriate only for patients over 40 years of age, are:

- Prolonged EMAT, cconsider LV systolic dysfunction
- Consider LV systolic dysfunction [*reason block*]
- Consider severe LV systolic dysfunction with diastolic dysfunction [*reason block*]
- Consider elevated LV filling pressure
- S3 detected -consider acute heart failure in presence of dyspnea

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 13 2007

Inovise Medical, Inc.
c/o Mr. Steve C. Hesler
Director, Quality and Regulatory
10565 SW Nimbus Avenue, Suite 100
Portland, Oregon 97223-4311

Re: K070136
Trade Name: SDI Modification to AUDICOR® 200 System
Regulation Number: 21 CFR 870.2340 and 870.1875
Regulation Name: Electrocardiograph and Stethoscope
Regulatory Class: Class II
Product Code: DPS and DQD
Dated: January 15, 2007
Received: January 16, 2007

Dear Mr. Hessler:

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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

B Zuckerman for

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

Enclosure

K070136

Indications for Use

510(k) Number (if known):

Device Name: SDI Modification to AUDICOR ® 200 System

Indications For Use:

The Audicor 200 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 report for consideration by physicians. In addition, the Audicor 200 System can be used with an add-on laptop computer that allows data to be presented in the format of real-time and trended display of advanced parameters derived from simultaneous ECG data and heart sounds data.

The 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, and is for use on adults (≥ 18 years).

Prescription Use ✓ 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)

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Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K070136