K080602

SEP 2 5 2008

Summary of Safety and Effectiveness

As required by 21 CFR, part 807.92

Submitted By:	Inovise Medical, Inc. 10565 SW Nimbus Ave, Suite 100 Portland, OR 97233-4311 Phone 503-431-3849 Fax 503-431-3801
Contact:	Kendra Rathkey Manager, Quality and Regulatory
Date Prepared:	August 26, 2008
Proprietary Name:	AUDICOR Sensor 2.0 and 3.0
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 are a family of dual-function sensors for use on adult patients (≥ 18 years) for acquisition of both heart sounds and ECG electrical signals and to transmit these signals to a compatible Audicor system to allow for the evaluation of patient status, to aid in diagnosis, and to determine effects of treatment on ECG and hemodynamics. There are disposable and reusable versions of the Audicor Sensor. Both can be used in the collection of resting ECG reports. The disposable Audicor Sensor is also intended for longer term monitoring applications of up to 48 hours.
Device Description:	The Audicor Sensors 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, and include a microphone for detection of heart sounds. The devices are intended for use on the chest wall in the V3 and/or V4 positions. Audicor sensors are available in two versions: 1) Single-use disposable sensors, for use up to 48 hours 2) Durable reusable sensors
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 10993-1:2003, Biological Evaluation of Medical Devices – Evaluation and testing.
Substantial Equivalence:	The Audicor Sensors are substantially equivalent to the Audicor™ COR Sensor (K030316). Modifications include: • Extended contact duration up to 48 hours for single-use sensor • Added reusable sensor to the product line
Technological Characteristics:	The Audicor sensors included in this submission are technologically equivalent to the predicate in that all are dual function sensors (ECG/heart sounds detection) and all are designed for use with Audicor-enabled ECG/heart sounds systems.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 2 5 2008

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

Re: K080602
Trade/Device Name: Audicor Sensors 2.0 and 3.0
Regulation Number: 21 CFR 870.2360
Regulation Name: Electrocardiograph electrode
Regulatory Class: Class II
Product Code: DRX, DQD
Dated: September 19, 2008
Received: September 22, 2008

Dear Ms. Rathkey:

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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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,

Donna R. Vochmer

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 (if known): K080602

Device Name: Audicor Sensor 2.0 and 3.0

Indications For Use:

The Audicor® Sensors are a family of dual-function sensors for use on adult patients (≥ 18 years) for acquisition of both heart sounds and ECG electrical signals and to transmit these signals to a compatible Audicor system to allow for the evaluation of patient status, to aid in diagnosis, and to determine effects of treatment on ECG and hemodynamics.

There are disposable and reusable versions of the Audicor Sensor. Both can be used in the collection of resting ECG 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)

Donna R. Kochman

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K080602