Attachment 3

AUG - 7 2003

Summary of Safety and Effectiveness
As required by 21 CFR, part 807.92

Submitted By:	Inovise Medical, Inc. 1025 Industrial Parkway, Suite C Newberg, OR 97132 Fax 503.538.8868
Contact:	Kendra Rathkey Tel 503.554.4277
Date Summary Prepared:	February 14, 2003 (revised June 24, 2003)
Proprietary Name:	Audicor™ Sensor
Common/Usual Name:	ECG Electrode & Heart Sound Transducer.
Classification:	21 CFR 870.2360 ECG Electrode, Class II, Product Code: DRX 21 CFR 870.2860 Heart Sound Transducer, Class II, Product Code: JOO
Performance Standards:	AAMI EC12:2000 (Disposable ECG Electrodes) AAMI EC53:1995 (ECG Cables and Lead Wires)
Intended Use:	The Audicor™ Sensor is a single-use, disposable medical device designed for short duration contact (up to 1 hour) for use at the V4 ECG electrode position to acquire both heart sounds and ECG electrical signals when attached to the body surface of a resting, adult (18+ years of age) patient, and to transmit these signals to compatible electrocardiographs and physiological recorders/monitors. Such equipment is commonly located in hospitals, doctor's offices and emergency vehicles.
Device Description:	The sensor is a single use, non-sterile, disposable medical device. When used with the Audicor Adaptor the device is designed to perform the functions of both a standard resting ECG Electrode by acquiring ECG signals and an Electronic Stethoscope by acquiring heart sounds from the surface of a patients skin. The device is intended for use on the surface of an adult patient's skin in the V4 electrode position on the chest.
Test Summary & Conclusion:	The sensor was tested to the applicable requirements of the performance standards, identified above, and shown to comply. Laboratory and bench testing indicates compliance

to the standard.

Biocompatibility for the hydrogel, the primary patient contact material of the sensor, was evaluated. Test results demonstrate that the material was found acceptable for cytotoxicity, primary skin irritation, and delayed dermal contact sensitization.

Based on the results of the engineering/design level and biocompatibility tests, it is concluded that the sensor performs as expected and compares well, in terms of overall performance to the selected predicate devices and raises no new questions with regard to safety and efficacy.

Substantial Equivalence: The Inovise Medical Audicor Sensor is substantially equivalent to the Kendall-LTP Disposable ECG electrode (K953649) and the E-Scope Electronic Stethoscope.

Technological Characteristics: The table below contains the comparison of features and principles of operation between the Audicor Sensor and other selected predicate devices.

Feature	Inovise Medical, Inc Audicor Sensor	Kendall Disposable ECG Electrode	E-Scope Electronic Stethoscope
510(k) Identifier	K030316	K953649	K961301
Meets EC12-2000 Standard	Yes	Yes	No
Meets ISO 10993 Standard	Yes	Yes	Unknown
Disposable Device	Yes	Yes	No
Used on Patient Skin Surface	Yes	Yes	Yes
ECG Electrode Functionality	Yes	Yes	No
Used in V4 position	Yes	Yes	Yes and other locations
Uses Conductive Hydrogel	Yes	Yes	No
Primary Packaging	Paper/Poly/Foil Pouch	Paper/Poly/Foil Pouch	Durable device
Acquires Heart Sounds	Yes	No	Yes
Uses Microphone	Yes	No	Yes
Frequency Range	20 – 660 Hz (nominal)	N/A	10 – 2000 Hz
Operating Temperature	10°C to 35 °C	Unknown	Unknown

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG - 7 2003

Inovise Medical, Inc.
c/o Mr. John C. So
Underwriters Laboratories, Inc.
2600 N.W. Lake Road
Camas, WA 98607

Re: K030316
Trade Name: Audicor™ COR Sensor Model M200
Regulation Number: 21 CFR 870.2360 and 21 CFR 870.1875
Regulation Name: Electrocardiograph Electrode and Stethoscope
Regulatory Class: Class II (two)
Product Code: DRX and DQD
Dated: July 29, 2003
Received: July 30, 2003

Dear Mr. So:

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.

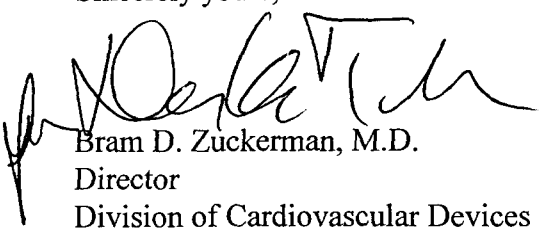
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 (301) 594-4646. 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 (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



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

Enclosure

Attachment 2

Indications for Use Statement

Applicant: Inovise Medical, Inc.
510(k) Number (if known): K030316
Device Name: Audicor Sensor

Indications for use:

The Audicor™ Sensor is a single-use, disposable medical device designed for short duration contact (up to 1 hour) for use at the V4 ECG electrode position to acquire both heart sounds and ECG electrical signals when attached to the body surface of a resting, adult (18+ years of age) patient, and to transmit these signals to compatible electrocardiographs and physiological recorders/monitors. Such equipment is commonly located in hospitals, doctor's offices and emergency vehicles.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓
(per 21 CFR 801.109)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K030316