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 Phone 503-554-4291 Fax 503-538-8868
Contact:	Steve Hesler Director, Quality and Regulatory
Date Summary Prepared:	July 10, 2003
Proprietary Name:	Audicor™ Upgrade System
Common/Usual Name:	Electrocardiograph
Classification:	870.2340, 74 DPS
Performance Standards:	UL 2601-1 IEC 60601-2-25 EN 60601-1-2 ANSI/AAMI EC 11
Intended Use:	The Audicor Upgrade System, when used with Audicor Sensors in the V3 and V4 positions on the chest wall, is intended for use in acquiring, analyzing and reporting ECG and heart sounds (phonocardiograph) data and to provide interpretation of the data for consideration by physicians. The Audicor Upgrade System is an add-on device designed to work with the following electrocardiographs: GE Mac 8 GE Mac Vu GE Mac 5000 Philips Pagewriter XL The interpretations of ECG and heart sound data offered by the device are only significant when used in conjunction with physician overread as well as consideration of all 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 Upgrade System is a pocket PC with proprietary software that can be used with several models of existing electrocardiographs to allow clinicians access to the COR (correlated audioelectric cardiography) report including graphical display of MI and LVH conditions as well as display of heart sound waveforms and identification of S3 and S4 heart sounds.
Test Summary & Conclusion:	The Audicor Upgrade System was tested to the applicable requirements of the performance standards, and shown to comply. Laboratory and bench testing indicates compliance to the standard. Based on the results of the engineering/design level tests, it is concluded that the Audicor Upgrade System 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 Upgrade System is substantially equivalent to the Mortara Instrument ELI 200+ with Audicor Electrocardiograph (K031182).

Technological Characteristics: The Audicor Upgrade System and the predicate device are technologically equivalent in that both acquire 12 lead ECG and heart sounds data from adult patients then present the data in the COR report format which includes graphic display of MI and LVH conditions along with detection and display of S3 and S4 heart sounds.

Predicate Device Comparison Table

Feature	ELI 200+ Electrocardiograph with Audicor COR	Audicor Digital Upgrade Box System
Manufacturer	Mortara Instrument, Inc.	Inovise Medical, Inc.
510(k) Identifier	K031182	
ECG Waveform Acquisition	Yes	Yes (through host lead set)
Interprets ECG Waveform Data	Yes	Yes
ECG Waveform Report Output	Yes	Yes
LVH Detection Algorithm	Yes	Yes
MI (prior) Detection Algorithm	Yes	Yes
MI (acute) Detection Algorithm	Yes	Yes
Heart Sounds Waveform Acquisition	Yes	Yes
Displays S1 - S4 Heart Sounds	Yes	Yes (with informational statements)
Analysis Test Report Output	Yes, multiple formats	Yes, single format
Printer	Built into unit	Separate printer
Graphical Representation of MI and LVH Analysis Statements	Yes	Yes

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 31 2003

Inovise Medical, Inc.
c/o Mr. Steve C. Hesler
Director, Quality and Regulatory
1025 Industrial Parkway, Suite C
Newberg, OR 97132

Re: K032145
Trade Name: Audicor™ Upgrade System
Regulation Number: 21 CFR 870.2340
Regulation Name: Electrocardiograph
Regulatory Class: Class II (two)
Product Code: DPS
Dated: October 9, 2003
Received: October 14, 2003

Dear Mr. Hesler:

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 may be obtained 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

Indications for Use Statement

Applicant: Inovise Medical, Inc.
510(k) Number (if known): _____
Device Name: Audicor™ Upgrade System

Indications for use:

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The Audicor System is an add-on device designed to work with the following electrocardiographs:

GE Mac 8
GE Mac Vu
GE Mac 5000
Philips Pagewriter XL

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 all 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).

(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)

Dina Strauchen
(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K033 K032145