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 503-431-3837 Fax 503-431-3801
Contact:	Steve Hesler Director, Quality and Regulatory
Date Prepared:	November 4, 2004
Proprietary Name:	Liberty System
Common/ Usual Name:	Electrocardiograph
Classification:	870.2340, 74 DPS
Performance Standards:	AANSI/AAMI EC 11
Intended Use:	The Liberty 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 COR report for consideration by physicians. The Liberty System can be used as an add-on device to work in conjunction with select cardiographs, defibrillators, and patient monitors; or as a stand-alone electrocardiograph. 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 Liberty System is a pocket PC-based device that that can be used to allow clinicians access to the COR (correlated audioelectric cardiography) report including graphical display of MI, Ischemia, and LVH conditions as well as display of heart sound waveforms and identification of S3 and S4 heart sounds.
Test Summary & Conclusion:	The Liberty System was tested to the applicable requirements of the following standards, and shown to comply. • ANSI/AAMI EC-11 Standard for Diagnostic Electrocardiographic Devices • ANSI/AAMI EC 53 ECG Cables and Leadwires • 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: Particular requirements fo the safety of electrocardiographs • UL 60601-1 Standard for Medical Electrical Equipment: General Requirements for Safety
Substantial Equivalence:	The Inovise Medical Liberty System is substantially equivalent to the Audicor Cardiograph Expansion system (K032145) and the Mortara Instrument ELI 200+

with Audicor Electrocardiograph (K031182).

Technological Characteristics: The Liberty 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.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 2 2 2005

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

Re: K043074
Trade Name: Liberty System
Regulation Number: 21 CFR 870.2340
Regulation Name: Electrocardiograph
Regulatory Class: Class II (two)
Product Code: DPS
Dated: February 17, 2005
Received: February 18, 2005

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.

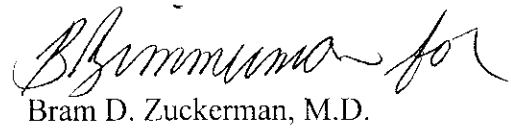
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish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

510(k) Number (if known): K043074

Device Name: Liberty System

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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)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K043074