

JUL 18 1997

SUMMARY STATEMENT OF SAFETY AND EFFECTIVENESS  
CARDIOMAGIC® 2000 SOFTWARE  
INSTROMEDIX, INC.  
510(k) NUMBER K964036

CardioMagic® 2000 Cardiac Monitoring System Software (CMS) is a productivity enhancing, office automation product. The intended users of CMS are physicians, clinics, and hospitals with cardiac patient follow-up and monitoring practices. CMS is a database software product, intended to involve competent intervention before any impact on health occurs. The software does not analyze the information. Clinical judgment and experience are required to check and interpret the printed reports, as part of the process of evaluating pacemaker performance, or patient ECG rhythms. There are no known contraindications for use of this device.

CardioMagic software is installed on an IBM compatible personal computer, which may also be networked to other PC's. An Instromedix LifeSigns Receiving Center™ (LRC) may be attached to the PC, to acquire transmitted data and waveforms from transtelephonic pacemaker monitors and ECG event recorders.

CardioMagic provides remote control of the LRC, presents the received waveforms and data on the computer screen, assists in editing, viewing, and organizing the received data, and provides database support for patient and device information, and provide reports.

The CardioMagic® 2000 CMS is substantially equivalent to previous CardioMagic products, PaceArt CPTS, and PaceBase.

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COMPARISON FEATURE/ SPEC	CARDIOMAGIC® 2000			CARDIOMAGIC® SAW		PACEART®	PACEBASE®
	MINUET™ ARRHYTHMIA	CONCERTO™ PACER FOLLOWUP	SYMPHONY™ BOTH	AM ARRHYTHMIA	ENHANCED BOTH	BOTH	BOTH
<b>COMPATIBILITY</b>							
SINGLE USER	YES	YES	YES	YES	YES	YES	YES
NETWORK COMPATIBLE	NO	NO	YES	YES	YES	YES	YES
IBM COMPATIBLE COMPUTERS	YES	YES	YES	YES	YES	YES	YES
OPERATING SYSTEM	WIN 95	WIN 95	WIN 95	DOS, WIN,WIN 95	DOS, WIN,WIN 95	DOS, WIN,WIN 95	DOS
TRANSTELEPHONIC RECEPTION	YES	YES	YES	YES	YES	YES	YES
IN-OFFICE ECG RECEPTION	YES	YES	YES	YES	YES	YES	YES
<b>SCREEN TOOLS</b>							
ECG STRIPS VIEWING	YES	YES	YES	YES	YES	YES	YES
SCREEN CALIPERS	YES	YES	YES	YES	YES	YES	NO
EDIT TRANSMISSIONS	YES	YES	YES	YES	YES	YES	YES
CONTEXT SENSITIVE HELP SUPPORT	YES	YES	YES	NO	NO	UNK	NO
RECEIVER CONTROL	YES	YES	YES	YES	YES	YES	YES
SOFTWARE ECG FILTERS	YES	YES	YES	NO	NO	YES	NO
<b>PACER FUJ</b>							
DISPLAY/RECORD ECG AND PACEMAKER PULSE EVENTS	NA	NO	YES	NA	YES	YES	YES
MAGNET MODE MARKERS	NA	YES	YES	NA	YES	YES	NO
NON-MAGNET AND MAGNET MODE ECG COLLECTION	NA	YES	YES	NA	YES	YES	NO
MANUAL ENTRY OF MAGNET RATE	NA	YES	YES	NA	YES	YES	YES
AUTOMATICALLY MEASURES PACER PULSEWIDTH	NA	NO	NO	NA	NO	YES	YES
MANUAL PACER PULSE DATA ENTRY	NA	YES	YES	NA	YES	YES	YES
RECORDS PACER PULSE DATA FROM TRANSMITTER	NA	YES	YES	NA	YES	YES	YES
MEASURES PACER PULSE WIDTH	NA	NO	YES	NA	YES	YES	YES
<b>ECG FUJ</b>							
SUPPORT OF IMX 3X FORMATS	YES	YES	YES	YES	YES	NO	NO
SUPPORT OF M, IMX 1X FORMATS	YES	YES	YES	YES	YES	YES	YES
AUTOMATICALLY DETERMINES HEART RATE	YES	YES	YES	NO	NO	YES	NO
ON-SCREEN EDITING OF ECG	YES	YES	YES	YES	YES	YES	NO
<b>INTERFACES</b>							
INTERFACES TO EXTERNAL ECG TRANSTELEPHONIC RECEIVER	YES	YES	YES	YES	YES	YES	YES
RECEIVES DIGITIZED ECG SIGNALS VIA SERIAL PORT	YES	YES	YES	YES	YES	YES	YES
IMPLANT INTERROGATOR CONNECTION INTERFACE	NO	NO	YES	NO	NO	YES	YES
PRINTER INTERFACE	YES	YES	YES	YES	YES	YES	YES
REMOTE USER SUPPORT	YES	YES	YES	NO	YES	YES	NO
AUTODIALER	NO	NO	YES	NO	NO	YES	NO
<b>OUTPUTS</b>							
HARDCOPY REPORT GENERATION	YES	YES	YES	YES	YES	YES	YES
FILE TRANSFER	YES	YES	YES	YES	YES	YES	YES
FAX REPORTS	YES	YES	YES	NO	YES	YES	NO
MAILING LIST/DATA MERGE	YES	YES	YES	YES	YES	YES	NO
ELECTRONIC DATA TRANSFER/MERGE	YES	YES	YES	NO	YES	YES	NO
<b>DATABASE</b>							
DATA BASE STORAGE AND RETRIEVAL	YES	YES	YES	YES	YES	YES	YES
DATABASE SEARCH & FILTERS	YES	YES	YES	YES	YES	YES	YES
RELATIONAL DATA BASE OF PATIENT DEMOGRAPHIC INFORMATION, LEAD AND ELECTRODE INFORMATION, INSURANCE INFORMATION, REFERRING PHYSICIAN INFORMATION	YES	YES	YES	YES	YES	YES	YES
RELATIONAL DATA BASE OF IMPLANT INFORMATION, PROGRAMMING PARAMETERS, THRESHOLDS,	NO	YES	YES	YES	YES	YES	YES
DEVICE DICTIONARY	NO	YES	YES	NO	YES	YES	YES
<b>SCHEDULER</b>							
TELEPHONE CALLING SCHEDULE	NO	YES	YES	YES	YES	YES	YES
OFFICE CALL SCHEDULING	NO	YES	YES	YES	YES	YES	YES
<b>SECURITY</b>							
SECURITY KEY	YES	YES	YES	YES	YES	UNK	UNK
SECURITY CODE	NO	NO	YES	YES	YES	UNK	YES
NET SECURITY (VIA NETWORK)	YES	YES	YES	YES	YES	UNK	UNK

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The primary purpose of CardioMagic, PaceArt and PaceBase software products is to provide to cardiac clinicians and automated computer system for tracking cardiac patients. These systems utilize a commercial relational database system. The database provides fields for storing device information such as: threshold, elective replacement intervals, device parameters and measurements, and telemetry data; and patient information which includes contacts and scheduled appointments. These systems store ECG signals and related data. The CardioMagic, PaceArt and PaceBase systems are application programs which operate on IBM compatible personal computers. Unlike the PaceArt CPTS product, CMS does not perform any waveform analysis on a patient's ECG. Thus, CardioMagic 2000 is substantially equivalent to previous CardioMagic products, PaceArt CPTS, and PaceBase.

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*The device does not sound any real-time  
alarm  
Chal <sup>MD</sup>  
July 18, '97*



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Herbert H. Semler, M.D.  
Instromedix, Inc.  
One Technology Center  
7431 N.E. Evergreen Parkway  
Hillsboro, Oregon 97124-5898

JUL 18 1997

Re: K964036  
CardioMagic® 2000 Software  
Regulatory Class: II (two)  
Product Code: 74 DXH  
Dated: April 15, 1997  
Received: April 21, 1997

Dear Dr. Semler:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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.

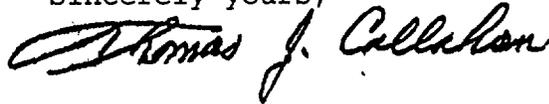
If your device is classified (see above) into either class II (Special Controls) or class III (Pre-market Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your pre-market notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

Page 2 - Herbert H. Semler, M.D.

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,



Thomas J. Callahan, Ph.D.  
Director  
Division of Cardiovascular,  
Respiratory, and Neurological Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

510(k) Number (if known): K964036

Device Name: CardioMagic® 2000 Software

Indications For Use:

Transtelephonic monitoring of arrhythmia and/or pacemaker implant patients that do not require emergency medical intervention.  
In-office acquisition and display of single and/or multi-lead ECG.  
Collection, storing, reporting, transfer, and management of patient(s) health information.

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

\_\_\_\_\_  
Concurrence of CDRH, Office of Device Evaluation (ODE)

*[Handwritten Signature]*  
John A. Carrillo

(Division Sign-Off)  
Division of Cardiovascular, Respiratory,  
and Neurological Devices

Prescription Use X  
(Per 21 CFR 801.109)

510(k) Number \_\_\_\_\_