K033488

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JUL - 7 2004

510(k) Summary
for
CMI Magnetocardiograph

1. SPONSOR

CardioMag Imaging, Inc.
450 Duane Avenue, Schenectady, New York 12304

Contact Person: Steve Karr, Ph.D.
Telephone: 518 381 1000, ext.37 e-mail: skarr@cardiomag.com

Date Prepared: June 29, 2004

2. Device Name

Proprietary Name: CMI Magnetocardiograph
Common/Usual Name: magnetocardiograph
Classification Name: to be determined

3. PREDICATE DEVICES

Hewlett Packard, model 1511B	ECG	K760542
Neuromag-122	magnetoencephalograph	K962764

4. DEVICE DESCRIPTION

This device integrates an array of magnetic detectors with data acquisition hardware/software for the purpose of measuring the magnetic signals generated by the electrical current flowing in the heart. The detectors are housed in a vertically adjustable holder. The patient bed moves horizontally in orthogonal directions allowing the acquisition of multiple datasets for different locations above the torso. Three standard ECG electrodes are placed on each wrist and one ankle of the subject to provide a reference signal for synchronization of multiple MCG datasets.

The MCG data is preprocessed and displayed as either real time traces, averaged traces, or as multi-dimensional color maps.

5. INTENDED USE

The CMI Magnetocardiograph is intended for use as tool which non-invasively measures and displays the magnetic signals produced by the electric currents in the heart.

6. Technological Characteristics and Substantial Equivalence

The CMI Magnetocardiograph is substantially equivalent to the Hewlett Packard ECG [510(k) number K760542] and the Neuromag Ltd. Magnetoencephalograph (MEG) called the Neuromag-122 [510(k) number K962764] in safety and effectiveness. Two tables, H.1 and H.2, are presented to illustrate the similarities and differences between the CMI Magnetocardiograph and its predicates.

Comparison Tables

Table H.1

Parameter	**CMI Magnetocardiograph**	**Hewlett Packard ECG**
No. of detectors or channels	9	5
Detector (or Sensor)	SQUID – no contact to subject	Electrode – contacts subject
Signal detected non-invasively	magnetic	Electrical
Waveform morphology	Similar to ECG	
Coverage	Four acquisitions to cover entire heart	One acquisition
Patient position	Supine	Supine or standing

Table H.2

Parameter	**CMI Magnetocardiograph**	**Neuromag-122 MEG**
No. of SQUID detectors/channels	9 (36 effective via re-positioning)	122
Signal detected	magnetic	Magnetic
Operating Principle	Superconducting flux transformer coupled with DC-SQUID controlled by analog flux-locked loop	Superconducting flux transformer coupled with DC-SQUID controlled by analog flux-locked loop
Gradiometer	Second order	Two orthogonal planar-first order gradiometers per location
Intersensor Spacing	40 mm	43-44 mm
Magnetic field localization	Yes	Yes
Cryogen Used	Liquid Helium	Liquid Helium
Gantry	Floor mounted	Floor mounted
Coverage	Four acquisitions to cover	One acquisition to cover

	entire heart	entire head
Patient position	Supine	Sitting or supine
Magnetically shielded room	Not required	Required

The basis for equivalence to the 5-lead Electrocardiograph predicate is that the CMI Magnetocardiograph produces magnetic waveforms (or traces) very similar in morphology to the electrical waveforms produced by the 5-lead Electrocardiograph, both waveforms emanating from the human heart. Data, taken from human subjects, is presented in Appendix H (Substantial Equivalence Information) to support this claim.

The basis for equivalence to the Magnetoencephalograph is that the Magnetoencephalograph (MEG) predicate and the magnetocardiograph (MCG) both use very similar technology (SQUIDs) and both measure the magnetic field emanating from a source – they are functionally equivalent. Appendix H presents data to support this claim.

Safety

The CMI Magnetocardiograph uses liquid Helium cooled sensors, which are housed in a thermally insulated cryostat, the outside temperature of which is at ambient temperature. In the highly unlikely event of the accidental rapid evaporation of the cryogen, the flow of gas would be upward, away from the subject. Refill of the cryostat is easily accomplished following the instructions and illustrations in the hardware manual. Since the device is entirely passive, does not touch the subject, and is housed in an electrically neutral fiberglass housing, the system is at least as safe as electrical ECG systems for both the operator and the subject. Comparable to the Neuromag-122 MEG system, the sensors make no contact to the subject. During a pilot study involving hundreds of subjects, there are no instances of any discomfort or pain to the patient, nor have any safety issues arisen while obtaining cardiac data from a subject.

7. PERFORMANCE TESTING

The device was tested by the Underwriters Laboratories and found to comply with requirements for fire, casualty and shock hazards covering UL equipment Class 1, and judged to be eligible for Classification and Follow-Up Service. The result is that CardioMag Imaging, Inc. (CMI) is authorized to use the UL marking, and is assigned UL # 51LB. Underwriters Laboratories also conducted Electromagnetic Compatibility Testing, the result being a Compliance Certificate given to CMI. Details can be found in Appendix D.

Extensive on-site testing at clinical sites shows that the device performs to specifications in a clinical environment. Clinical data was also used as part of the indication for substantial equivalence to 5-lead ECG (Appendix H).

Bench tests are applied to all units which leave CMI to be used for R&D investigations. Results of the bench testing are reviewed to assess pass or failure of the components and the system.

Each new version of the software is tested in accordance with FDA guidelines. Results of performance testing for the latest version of the software are documented in Appendix C.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL - 7 2004

CardioMag Imaging, Inc.
c/o Steve Karr, Ph.D.
Program Manager
450 Duane Avenue
Schenectady, NY 12304

Re: K033488
Trade Name: CMI Magnetocardiograph, Model 2409
Regulation Number: 21 CFR 870.2340
Regulation Name: Electrocardiograph
Regulatory Class: Class II (two)
Product Code: 74 DPS
Dated: April 9, 2004
Received: April 12, 2004

Dear Dr. Karr:

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.

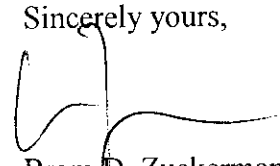
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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) 594-4648. 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

Indications for Use

510(k) Number (if known): K033488

Device Name: CMI 2409 Magnetocardiograph

Indications For Use:

The CMI Magnetocardiograph is intended for use as a tool that non-invasively measures and displays the magnetic signals produced by the electric currents in the heart.

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)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K033488