

K973403

510(k) Summary of Safety and Effectiveness

Date September 2, 1997

MAR 12 1998

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

Submitter Marquette Medical Systems
8200 West Tower Avenue
Milwaukee, WI 53223 USA

Contact Person Dianne Schmitz
Corporate Regulatory Affairs
Marquette Medical Systems

Phone: (414)362-3230

Common / Usual Device Name Electrocardiograph

Trade / Proprietary Device Name CardioSmart ST

Classification Name(s)

The classification names, classification panels, and regulation citations include the following:

21 CFR 870.2340	Electrocardiograph	74DPS
21 CFR 870.1025	Arrhythmia detector and alarm	74DSI

Legally Marketed Predicate Devices

The CardioSmart ST, is substantially equivalent to devices already in legal commercial distribution. These predicate devices include:

Marquette Hellige CardioSmart	K950989
Marquette Hellige CardioSys	K951130
Marquette Responder 1500	K903644

Device Description CardioSmart ST is a portable ECG data acquisition and recording system designed and manufactured by Marquette Hellige GmbH.

- CardioSmart ST allows the user to
- record resting ECGs,
 - measure and interpret the ECGs,
 - perform ECG stress tests.

Intended Use CardioSmart ST is intended to be used for resting and stress test

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ECG and for recording ECG in real-time without arrhythmia detection.

- CardioSmart ST is intended to be used by trained operators when ECG records are required in the judgment of a physician.
- CardioSmart ST is not intended for use as a vital signs physiological monitor.
- CardioSmart ST offers no diagnostic opinion to the user. Instead, it provides interpretive statements for which the physician renders his/her own medical opinion.
- CardioSmart ST is not designed for intracardial use.
- CardioSmart ST is not intended for home use.

The intended use of CardioSmart ST is a subset of the intended use of the predicate devices.

Technology

The CardioSmart ST hardware architecture is identical to the predicate device CardioSmart.

All parts of the software which determine the medical functionality of the CardioSmart ST were re-used from the predicate devices.

Performance & Conclusion CardioSmart ST complies with the following standards:

ANSI/AAMI EC11-1991, ANSI/AAMI ES1-1993, IEC 601-1, IEC 601-1-2 and IEC 601-2-25.

CardioSmart ST passed the EC type-examination and thus bears the CE mark.

The following quality assurance measures were applied to the development of CardioSmart ST:

Requirements specification and design reviews, code inspections, software and hardware testing, safety testing, environmental testing, final validation testing by an independent test group.

The results of these measures demonstrated that CardioSmart ST is as safe, as effective, and performs as well as the predicate devices CardioSmart, CardioSys, and Responder 1500.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 12 1998

Ms. Dianne Schmitz
Marquette Medical Systems
8200 West Tower Avenue
Milwaukee, WI 53223

Re: K973403
CardioSmart ST
Regulatory Class: III (three)
Product Code: 74 LOS
Dated: December 19, 1997
Received: December 22, 1997

Dear Ms. Schmitz:

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.

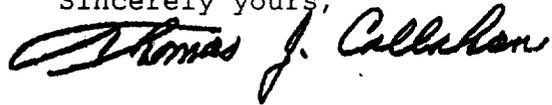
If your device is classified (see above) into either class II (Special Controls) or class III (Pre-market Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially 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 premarket 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 - Ms. Dianne Schmitz

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: K973403; 510(k) filed September 5, 1997

Device Name: CardioSmart ST

Indications For Use:

CardioSmart ST is an ECG data acquisition and recording system designed and manufactured by Marquette Hellige GmbH.

CardioSmart ST is intended to be used for resting ECG and stress test ECG and for recording ECG in real-time without arrhythmia detection. It is intended to be used by trained operators when ECG records are required in the judgement of a physician.

ECG may be interpreted by optionally available analysis program. CardioSmart ST offers no diagnostic opinion to the user. Instead, it provides interpretive statements for which the physician renders his/her own medical opinion.

CardioSmart ST is not intended for use as a vital signs physiological monitor.

CardioSmart ST is not designed for intracardial use.

CardioSmart ST is not intended for home use.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Mr. Pugh
(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K973403

Prescription Use
(Per 21 CFR 801.109)

OR

Over-The-Counter Use

(Optional Format 1-2-96)