OCT 6 1998

K981024

SECTION 2 - SUMMARY AND CERTIFICATION

2.1 510(k) Summary of Safety and Effectiveness

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 W. Tower Avenue
Milwaukee, WI 53223
Telephone: (414) 355-5000
FAX: (414) 362-3553

Contact Person:

Kristin Pabst

Device:

Trade Name: **QT Dispersion and T wave Analysis System (QT Guard Analysis System)**
Classification Name: Computer, diagnostic, programmable

Predicate Device:

Marquette 12SL Analysis Program

Device Description:

QT Guard Analysis System is a software program for measuring the QT interval dispersion and T wave complexity from simultaneously acquired 12-lead ECG.

Intended Use:

QT Guard Analysis System is intended to be used in a hospital or clinic environment by competent health professionals

♦ QT Guard Analysis System is intended to perform the analysis of simultaneously acquired 12-lead ECG for obtaining the measurements of QT interval dispersion and T wave complexity.

♦ QT-Guard Analysis System is intended to provide only the measurements of the QT dispersion and T wave complexity and it is not intended to produce any interpretation of those measurements or diagnosis.

♦ The QT dispersion & T wave complexity measurements produced by QT-Guard Analysis System are intended to be used by qualified personnel in evaluating the patient in conjunction with patient's clinical history, symptoms, other diagnostic tests, as well as the professional's clinical judgment.

♦ QT Guard Analysis System is intended for adult patient populations.

Technology:

QT Guard Analysis System employs technology similar to that used in the predicate device.

Performance:

The following quality assurance measures were applied:
to the development of PHi-Res analysis.
Requirements specification reviews, code inspections,
software testing and laboratory tests of the QT Guard analysis.

The results of these measurements demonstrated that QT Guard analysis is as safe, as effective, and performs as well as the predicate device, Marquette 12SL analysis program.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 6 1998

Ms. Kristin Pabst
Marquette Medical Systems, Inc.
8200 West Tower Avenue
Milwaukee, WI 53223

Re: K981024
QT Dispersion and T Wave Analysis Program
(QT-Guard Analysis System)
Regulatory Class: III (three)
Product Code: 74 LOS
Dated: July 15, 1998
Received: July 16, 1998

Dear Ms. Pabst:

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 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). 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 (Premarket 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.

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/dsma/dsmamain.html".

Sincerely yours,

Thomas J. Callahan

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

Enclosure

K981024

SECTION 11 - INTENDED USE STATEMENT

510(k) Number (if known): Unknown - 510(k) filed March 18, 1998

Device Name: QT Dispersion and T wave Analysis Program (QT Guard Analysis System)

Indications For Use:

QT Guard Analysis System is intended to be used in a hospital or clinic environment by competent health professionals.

QT Guard Analysis System is intended to perform the analysis of simultaneously acquired 12-lead ECG for obtaining the measurements of QT interval dispersion and T wave complexity.

QT-Guard Analysis Program is intended to provide only the measurements of the QT dispersion and T wave complexity and is not intended to produce any interpretation of those measurements or diagnosis.

The QT dispersion and T wave complexity measurements produced by QT Guard Analysis System are intended to be used by qualified personnel in evaluating the patient in conjunction with patient's clinical history, symptoms, other diagnostic tests, as well as the professional's clinical judgment.

QT Guard Analysis System is intended for adult patient populations.

Prescription Use ✓

Mark Kramer

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

510(k) Number _____