K972199

SEP 25 1997

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: Signal-Averaged High Resolution P Wave Analysis (PHi-Res) Option
Classification Name: Computer, diagnostic, programmable

Predicate Device:

Marquette High Resolution ECG Option for MAC-Series Electrocardiographs

Device Description:

PHi-Res analysis is a software option for Marquette MAC-series electrocardiographs for high resolution P wave analysis.

Intended Use:

PHi-Res analysis is intended to be used in a hospital or clinic environment by competent health professionals for recording low amplitude/high frequency components of the surface electrocardiogram for P wave analysis.

♦ PHi-Res analysis is intended to perform signal averaging of the atrial wave (P wave) from high-resolution ECG by P wave triggering method and analyzing the averaged P wave for its measurements.

♦ PHi-Res analysis is intended to provide only the measurements of the signal averaged P wave. PHi-Res is not intended to produce any interpretation of those measurements or any kind of diagnosis.

♦ The signal averaged P wave measurements produced by PHi-Res 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 judgement.

♦ PHi-Res is intended for patient populations including adult and pediatric.

Technology:

PHi-Res analysis employs the same technology as the predicate device.

Performance:

The following quality assurance measures were applied:

Requirements specification reviews, code inspections, software testing and field tests of the PHi-Res analysis.

The results of these measurements demonstrated that PHi-Res analysis is as safe, as effective, and performs as well as the predicate device, Marquette High Resolution Option for MAC-Series Electrocardiographs.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20856

SEP 25 1997

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

Re: K972199
Signal-Averaged High Resolution P Wave Analysis (PHi-Res, Software Version 1A) for MAC-Series ECG only
Regulatory Class: II (two)
Product Code: 74 DPS
Dated: June 10, 1997
Received: June 11, 1997

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 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/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

SECTION 11 - INTENDED USE STATEMENT

510(k) Number (if known): Unknown - 510(k) filed May 30, 1997 K972199

Device Name: Signal-Averaged High Resolution P Wave Analysis (PHi-Res)

Indications For Use:

PHi-Res is a software option for Marquette ECG analysis systems for high resolution P wave analysis. PHi-Res is intended to be used in a hospital or clinic environment by health care professionals for recording low amplitude/high frequency components of the surface electrocardiogram for P wave analysis.

PHi-Res analysis is only intended to provide the measurements of the signal averaged P wave and is not intended to provide any interpretation of those measurements or any kind of diagnosis. The P wave measurements provided by PHi-Res analysis 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.

PHi-Res is intended for patient populations including adult and pediatric.

Alla A. Gall

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K972199

Prescription Use ✓
(Per 21 CFR 801.109)

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