DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Antony R. H. Fender
Official FDA Correspondent
Jack's Electrodes, Inc.
2227 East Crescent Drive
Altadena, California 91001

JAN 28 1998

Re: K974119
Trade Name: Disposable Needle Electrode (ALM and DLM)
Regulatory Class: II
Product Code: GXZ
Dated: September 4, 1997
Received: October 31, 1997

Dear Mr. Fender:

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 requirement, 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) 594-4659. 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,

for Celia M. Witten, Ph.D., M.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

FEB 6 1998

K974199

SECTION 2 - SUMMARY AND CERTIFICATION

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, Inc.
8200 W. Tower Avenue
Milwaukee, WI 53223
Telephone: (414) 355-5000
FAX: (414) 362-3553

Contact Person:

Kristin Pabst

Device:

Trade Name: Acute Cardiac Ischemia Time-Insensitive Predictive Instrument (ACI-TIPI) Option
Classification Name: Computer, diagnostic, programmable Detector and Alarm, Arrhythmia

Predicate Device:

Hewlett- Packard Model 1791A ACI-TIPI

Device Description:

Acute Cardiac Ischemia Time-Insensitive Predictive Instrument (ACI-TIPI) Option is a software option for Marquette MAC-series electrocardiographs to aid the physician's decision-making process in a chest pain setting by using patient age, gender, chest pain status and ECG features to provide the predicted probability of acute cardiac ischemia (which includes unstable angina pectoris and acute myocardial infarction).

Intended Use:

Acute Cardiac Ischemia Time-Insensitive Predictive Instrument (ACI-TIPI) Option is intended to be used in a hospital or clinic environment by competent health professionals utilizing recorded ECG data to produce a numerical score which is the predicted probability of acute cardiac ischemia. Like any computer-assisted ECG interpretation program, the Marquette ACI-TIPI evaluation and probability score is intended to supplement, not substitute for the physician's decision process. It should be used in conjunction with knowledge of the patient's history, the results of a physical examination, the ECG tracing, and other clinical findings.

ACI-TIPI is intended for adult patient populations.

Technology:

ACI-TIPI option employs the same technology as the predicate device.

Performance:

The following quality assurance measures were applied to the development of ACI-TIPI.

Requirements specification review, software testing and field tests of the ACI-TIPI analysis.

The results of these measurements demonstrated that ACI-TIPI analysis is as safe, as effective, and performs as well as the predicate device, Hewlett-Packard Model 1791A ACI-TIPI.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Rockville MD 20857

FEB 6 1998

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

Re: K974199
Acute Cardiac Ischemia Time-Intensive Predictive Instrument (ACI-TIPI) Option
Regulatory Class: III (three)
Product Code: 74 LOS
Dated: November 7, 1997
Received: November 10, 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

FEB 6 1998

SECTION 11 - INTENDED USE STATEMENT

510(k) Number (if known): Unknown - 510(k) filed August 29, 1997

Device Name: Acute Cardiac Ischemia Time-Insensitive Predictive Instrument (ACI-TIPI)

Indications For Use:

Acute Cardiac Ischemia Time-Insensitive Predictive Instrument (ACI-TIPI) Option is intended to be used in a hospital or clinic environment by competent health professionals . TIPI utilizes recorded ECG data along with patient demographic and chest pain status to produce a numerical score which is the predicted probability of acute cardiac ischemia. Like any computer-assisted ECG interpretation program, the Marquette ACI-TIPI evaluation and probability score is intended to supplement, not substitue for the physician's decision process. It should be used in conjunction with knowledge of the patient's history, the results of a physical examination, the ECG tracing, and other clinical findings.

ACI-TIPI is intended for adult patient populations.

M. Purl

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K974199

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