K980582

MAR 16 1998

Section 2
Summary and Certification
510(k) Summary
Date: February 13, 1998

1. **Establishment Information**

Manufacturer/Submitter:	Marquette Medical Systems 100 Marquette Drive Jupiter, FL 33468
Registration Number:	1051778
Contact Name/Phone #	Michael Laughran/ (561) 575-5000

2. **General Device Information**

Common/Usual Name:	ECG Lead Wire and Cable System
Trade/Proprietary Name:	Multi-Link Cable and Lead Wire Systems
Classification Name:	Patient transducer and electrode cable (including connector)
Device Classification:	Class II.
Performance Standards:	21CFR Part 898: Performance Standard for Electrode Lead Wire and Patient Cables. This Standard is effective on May 11, 1998 and was published in the Friday, May 9, 1997 Federal Register.

3. **Substantial Equivalence:** Multi-Link Cable and Lead Wire Systems is substantially equivalent to ConMed Corp. ECG Patient Cables and Leadwires which are currently legally marketed under 510(k) 933649.

4. **Device Description:** Multi-Link Cable and Lead Wire Systems are a reusable electrode cable systems used to transmit signals from patient electrodes to various electrocardiograph recorders / monitors for both diagnostic and monitoring purposes. This type of device is common to both the industry and to most medical establishments.

5. **Intended Use:** Multi-Link Cable and Lead Wire Systems are reusable electrode cable systems used to transmit signals from patient electrodes to various electrocardiograph recorders / monitors for both diagnostic and monitoring purposes. Multi-Link Cable and Lead Wire Systems are limited by the indications for use of the connected monitoring or diagnostic equipment. Such equipment is commonly located in hospitals, doctor's offices, and emergency vehicles, as well as in home use.

6. **Technological comparison to legally marketed predicate device:** the Multi-Link Cable and Lead Wire Systems technological characteristics are similar in comparison to the ConMed Corp. ECG Patient Cables and Leadwires

7. **Test Summary and Conclusion:** A comparison of the predicate device's production and both electrical and mechanical testing to AAMI ECGC-5/83 was made to the equivalent production, electrical and mechanical testing of the Multi-Link Cable and Lead Wire Systems. Testing also demonstrated that the Multi-Link Cable and Lead Wire Systems meet 21CFR Part 898: Performance Standard for Electrode Lead Wire and Patient Cables. Marquette Medical Systems has demonstrated that the use of the Multi-Link Cable and Lead Wire Systems is as safe and as effective, and performs substantially equivalent to its predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20856

MAR 16 1998

Mr. Michael Laughran
Marquette Medical Systems
100 Marquette Drive
Jupiter, FL 33458

Re: K980582
Multi-Link Cable and Lead Wire Systems
Regulatory Class: II (two)
Product Code: 74 DSA
Dated: February 13, 1998
Received: February 17, 1998

Dear Mr. Laughran:

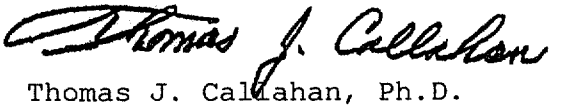
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have 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) 594-4649. 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, Ph.D.
Director
Division of Cardiovascular,
Respiratory, and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section 13
Indication for Use Statement

INDICATIONS FOR USE PAGE

510(K) Number (if known): Unknown - 510(k) filed February 13, 1998

Device Name: Multi-Link Cable and Lead Wire Systems

Indications for use:

Multi-Link Cable and Lead Wire Systems are electrode cable systems used to transmit signals from patient surface electrodes to various electrocardiograph recorders/monitors for both diagnostic and monitoring purposes. Use is limited by the indications for use of the connected monitoring or diagnostic equipment. Such equipment is commonly located in hospitals, doctors offices, emergency vehicles, as well as in home use.

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

Concurrence of CDRH, Office of device Evaluation (ODE)

Prescription Use X OR Over- The- Counter Use _____

(Per 21 CFR 801.109)

(Division Sign-Off)
Division of Cardiovascular, Respiratory, and Neurological Devices
510(k) Number K980582