K984263

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FM 34863
ISO 9001

FEB 2 1999

Summary and Certification
510(k) Summary
Date: November 25, 1998

1. Establishment Information:

Submittor:	EWC (Electri-Wire Corporation) N26 W23315 Paul Road Pewaukee, WI 53072-4061
Registration #:	9921058 (Owner/Operator)
Contact Person:	Timothy M. Davis
Contact Phone #:	(414) 548-3700 or 800-786-3707
Manufacturing:	EWC (Electri-Wire Corporation) 208 West Street Waupun, WI 53963
Registration #:	2183764

2. General Device Information:

Common Name:	ECG Cable and Leadwire System
Trade Name:	EWC: ECG II Cable and Leadwire System
Classification Name:	Patient transducer and electrode cable (including connector)
Device Classification:	Class II (21 CFR: part 870.2900)
Performance Std's.:	- 21 CFR Part 898: Performance Standard for Electrode Leadwire and Patient Cables. This standard is effective on May 11, 1998 and was published in the Friday, May 9, 1997 Federal Register. - Voluntary Standard: ANSI/AAMI, EC53- 1995, ECG cables and leadwires. - Voluntary Standard: ANSI/AAMI, EC13-92, Standard, Cardiac monitors, heart rate meters and alarms; part 3.1.1.5 only. Color coding for labels and leadwire requirements will be met.

3. Substantial Equivalence: The EWC: ECG II Cable and Leadwire System is substantially equivalent to the Tronomed Patient Cable and Lead Wire Systems which were marketed under 510(k) numbers; K771645, K771027 and K770884.

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4. Device Description: The EWC: ECG II Cable and Leadwire System is a reusable electrode cable designed to transmit signals from the patient connect electrodes (not supplied by EWC) to various electrocardiograph recorders/monitors (not supplied by EWC) for both diagnostic and monitoring purposes. This device is common to both the industry and to most medical establishments. The EWC: ECG II Cable and Leadwire System is offered in a 3, 5, 7, and 10 lead design. All cables have detachable leadwires that have AAMI compatible plug (patient side) and are supplied with user defined patient electrode connectors (snap, banana, pin or gripper style).

5. Intended Use: The EWC: ECG II Cable and Leadwire Systems are reusable electrode cables used to transmit signals from the patient connected electrodes (not supplied by EWC) to various electrocardiographic recorders and/or monitors (not supplied by EWC) for both diagnostic and monitoring purposes. The EWC: ECG II Cable and Leadwire System is limited by the indication for use of the connected monitoring or diagnostic equipment. Such equipment is commonly located in hospitals, doctor's offices, emergency vehicles, as well as in home use.

6. Technology comparison to legally marketed predicate device: The EWC: ECG II Cable and Leadwire System technological characteristics are similar, in comparison, to the Tronomed Patient Cable and Lead Wire Systems as identified in 3 above.

7. Test Summary and Conclusion: The EWC: ECG II Cable and Leadwire System was tested to the requirements of the mandatory performance standard defined in 21 CFR 898, as identified in 2 above, and shown to comply. The system was also designed and tested to the requirements of the ANSI/AAMI performance standard covering ECG Cables and Leadwires (EC53-1995). Laboratory testing indicates compliance to the standard. Test results were retained in the design history file. Color coding for the labels and leadwires comply with the ANSI/AAMI standard EC13-92 (Cardiac monitors, heart rate meters and alarms, part 3.1.1.5). Visual inspection confirms appropriate color coding.

Simulated use testing, using an ECG Simulator, a ECG Monitor and a Tektronix TDS 380 recording Oscilloscope , was also completed on a five lead version of the predicate device and the five lead version of the EWC: ECG II Cable and Leadwire System. Test results were reviewed and indicate favorable and similar performance of both cables. Results are retained as part of the design history file.

Based on the results of the engineering/design level test, along with the simulated use tests, it is felt that the EWC: ECG II Cable and Leadwire System performs as expected and compares well, in terms of overall performance to the selected Tronomed device (predicate device).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 2 1999

Mr. Timothy M. Davis
Corporate Director RA/QA
EWC
N26W23315 Paul Road
Pewaukee, WI 53072

Re: K984263
ECG II Cable and Leadwire System
Regulatory Class: II (two)
Product Code: DSA
Dated: November 25, 1998
Received: November 30, 1998

Dear Mr. Davis:

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, ²Misbranding by reference to premarket notification² (21CFR 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

"Indication for Use Statement"

INDICATION FOR USE PAGE

510(k) Number (if known): Unknown

Device Name: EWC: ECG II Cable and Leadwire System

Indication for use: The EWC: ECG II Cable and Leadwire Systems are reusable electrode cable systems used to transmit signals from patient electrodes (not supplied by EWC) to various electrocardiographic recorders and/or monitors (not supplied by EWC) for both diagnostic and monitoring purposes. The EWC: ECG II Cable and Leadwire System is limited by the indication for use of the connected monitoring or diagnostic equipment. Such equipment is commonly located in hospitals, doctor's offices, emergency vehicles, as well as in home use.

(Please do not write below this line - Continue on another page if required)

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 K984263