



FM 34863
ISO 9001

Summary and Certification

510(k) Summary

Date: August 6, 1998

1. Establishment Information:

Submitter: EWC (Electri-Wire Corporation)
N26 W23315 Paul Road
Pewaukee, WI 53072-4061

Registration #: 9921058 (Owner/Operator)

Contact Name: Timothy 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 Systems

Trade Name: EWC: ECG Cable and Leadwire Systems

Classification Name: Patient transducer and electrode cable (including connector)

Device Classification: Class II (21 CFR: part 870.2900)

Performance Std.: 21 CFR 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: The EWC: ECG Cable and Leadwire Systems is substantially equivalent to the Tronomed Patient Cable and Lead Wire Systems which were marketed under 510(k) numbers; K771645, K771027 and K770884.

4. Device Description: The EWC: ECG Cable and Leadwire Systems are reuseable electrode cables designed to transmit signals from the patient electrode (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 Cable and Leadwire Systems is offered in various configurations of cable types (3, 5, 7 and 10 lead versions), various lead styles (length, color, etc.) and various electrode connector configurations (snaps, grippers and pins).

5. Intended Use: The EWC: ECG Cable and Leadwire Systems are reusable electrode cable systems used to transmit signals from patient electrodes (not supplied by EWC) to various electrocardiograph recorders/monitors (not supplied by EWC) for both diagnostic and monitoring purposes. The EWC: ECG Cable and Leadwire 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, emergency vehicles, as well as in home use.

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

7. Test Summary and Conclusion: The EWC: ECG Cable and Leadwire Systems was tested to the requirements of 21 CFR 898 and shown to comply with the performance standard. Although the EWC: ECG Cable and Leadwire System was not designed to comply, in total, with the ANSI/AAMI EC53-1995, voluntary standard covering ECG Cables and Leadwires, a number of the test identified in the standard were performed, as necessary to evaluate the overall cable design and utility. Simulated use testing was also completed on both the predicate device cable and leadwire system and compared against the same tests conducted on the EWC: ECG Cable and Leadwire Systems and no significant difference in performance could be observed. Based on the results of the engineering/design testing, along with the simulated use performance testing (comparison testing), it is felt that the EWC: Cable and Leadwire Systems performs as expected and compares well, in terms of overall performance to the selected Tronomed device (predicate device).



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 23 1998

Mr. Timothy M. Davis
Corporate Director RA/QA
EWC Corporate Center
N26 W23315 Paul Road
Pewaukee, WI 53072-4061

Re: K982817
ECG Cable and Leadwire Systems
Regulatory Class: II (two)
Product Code: DSA
Dated: August 6, 1998
Received: August 11, 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 (Pre-market 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' (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, 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 Cable and Leadwire Systems**

Indication for Use: **The EWC: ECG Cable and Leadwire Systems are reusable electrode cable systems used to transmit signals from patient electrodes (not supplied by EWC) to various electrocardiograph recorders/monitors (not supplied by EWC) for both diagnostic and monitoring purposes. The EWC: ECG Cable and Leadwire 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, 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)

 Donk Telle
(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number 1982817