K992524

MAR - 1 2000

J. 510(k) SUMMARY

510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR §807.92.

Contact Person: Ken Kendricks
10630 Wiles Road
Coral Springs, FL 33067
Phone: (954)-345-9800 Ext. 1012
Fax: (954)-345-0507

Date Prepared: July 25, 1999

Trade Name: Patient Monitoring Cables for ECG, EKG, SpO2 and Blood Pressure Monitors.

Common Name: Patient Cables and Leadwires

Product Classification: Class II : Cardiolvascular 74 DSA, per 21 CFR section 870.2900.

Description/Intended Use

Advantage Medical Cables are produced using purchased 5 conductor cable and single conductor leadwire, both shielded and un-shielded, which is cut to various lengths, terminated with the appropriate type terminals and housed in a protective covering made from different types of FDA Grade thermoplastic elastomers, (polypropylene and TPR), using an injection molding process and custom built molds to achieve the desired shape and size. The cito-toxticity test results are in Attachment J1.

The most common cable configuration is of a three or five conductor cable with a metal or plastic connector terminated on one end by crimp or solder method, using various keyway configurations depending on the make and model of the monitor, for connection to the monitoring device, and the three or five conductors terminated into a yoke assembly for the leadwires to attach on the other end. The leadwires may be permanently attached to the yoke or terminated on one end with a .060 diameter pin and over molded with the mating DIN style connector and a snap or pinch type connector on the other end for connection to the patient electrodes. The leadwires may be shielded or unshielded construction. See Attachment E2-1 Patient Cable Drawing CB-71330R, and Illustration E1.

Advantage Medical Cables and leadwires are used in conjunction with various patient monitoring equipment such as ECG, EKG, SpO2 and Blood Pressure equipment for short term diagnostic monitoring. They are not intended to be used in any manner other than as the connection between the monitoring equipment and the electrode pads to monitor the signals between the patient and the transmitter/receiver.

Testing

Performance testing has been performed using the different types of monitors from the original equipment manufacturers, the OEM cables, Tronomed Cables and Advantage Medical Cables as described in the Performance Testing section, Attachment K.

Manufacturing Facility

Advantage Medical Cables, Inc., a division of Advantage Medical Electronics, Inc. (AME) is located at 10630 Wiles Road in Coral Springs, Florida 33076 and is housed in a 10,000 square foot fully air conditioned single story building. The molding and assembly areas are adequately lighted and are equipped with all the tools and equipment required to produce high quality cables and leadwires. Additional or special customer requirements are reviewed and tools and equipment purchased to meet their requirements.

AME is registered with the FDA as a manufacturer and refurbisher/rebuilder of medical equipment, number 1063285. A Class 1 CE mark has been applied for in order to sell AMC Cables and leadwires in the EEC.

All cables and leadwires are produced using a revision controlled engineering drawing and work order, see Attachment E2 & E5. Records are maintained for each manufacturing lot number and customer. Each cable is tested to ensure conformance to the customer or regulatory requirements. Traceability is sufficient to facilitate product recall if necessary using the lot numbers and shipping records.

All AMC equipment used for product acceptance testing is calibrated and traceable to NIST standards.

Advantage Medical Cable's quality system is in compliance with ISO 9002 and EN 46002. Internal and independent audits are conducted to ensure conformance to the quality manual and quality system procedures. Registration is scheduled for Q3/99.

All personnel are trained and/or qualified as applicable for the job assigned. Training records are maintained.

Summary

As shown in the engineering drawings and the photographic illustrations, except for the color of the cable and leadwires and subtle differences in the shape of the molded connectors and yokes, the AMC cables are identical in their function and performance characteristics as to the Tronomed cables.

The products are manufactured on similar type equipment, with exception to the size and make of the machine, and under the same general manufacturing conditions with exception to size and location of the facilities.

The minor differences in the characteristics noted do not effect quality, safety or functionality of the cable and leadwires manufactured by AMC.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR - 1 2000

Mr. Kenneth E. Kendricks
Vice President
Advantage Medical Electronics, Inc.
10630 Wiles Road
Coral Springs, FL 33076

Re: K992524
Trade Name: Patient Cables and Leads for Monitoring
(i.e. ECG, SP02 and BP)
Regulatory Class: (II)
Product Code: 74 DSA
Dated: December 9, 1999
Received: December 13, 1999

Dear Mr. Kendricks:

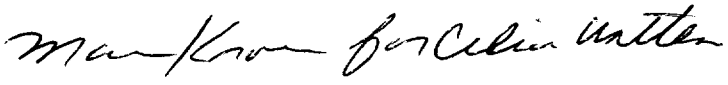
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 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, "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,



Celia M. Witten, Ph.D., M.D.
Acting Director
Division of Cardiovascular,
Respiratory, and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

C. INDICATIONS FOR USE OF THE DEVICE

510(k) Number: K992524

Device Name: Patient Monitoring Cables and Leadwires

Indications for Use:

These patient cables and leadwires are intended to be used with ECG, EKG, Sp02 and Blood Pressure monitoring devices.

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

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Mark Nichols for Celia Witten

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K992524