K070232

MAR 2 7 2007

Supporting Clinical Engineering Worldwide

510(k) Summary

Submitter Information:

American IV Products, Inc.
7485 Shipley Avenue
Harmans, MD 21077

Contact:

John Taylor
Director of Engineering
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Date Prepared:

January 19, 2007

Product Name:

Classification Name: Cable, Transducer and Electrode, Patient, (Including Connector)
Common Name: ECG Cables, Trunk and Patient Lead Wires
Proprietary Name: ECG Cables, Trunk and Patient Lead Wires

Predicate Device:

These AIV devices are substantially equivalent to the following legally marketed devices:

ConMed Corp: K945034, K933649

FSR1311, FSR565, FSR1303, FSR1534, FSR1390, FSR1590, FSR367, FSR1370, FSR1539, D8338II, D8538, FSP24-003R, DA24-03II, FSA24-003R, DL24-03II, FSP24-005R, DA24-05, FSA24-005R, DL24-05

GE Medical Systems: K980582, K970545, K964750, K960418

2017003-001, 411203-001, 411202-001, 412682-001, 412681-001

Description:

AIV's Electrocardiograph (ECG) cables (also sometimes referred to as trunk or leadwires) are replacements for similar cables manufactured by the Original Equipment Manufacturers (OEM) and other third party after market manufacturers for their respective monitors. The Trunk Cables connect the OEM patient monitor to the patient leadwires. The Leadwires connect the trunk cable to the skin mounted ECG electrodes.

These cables consist of connectors on each cable end and a shielded bulk cable. The cables are used to transfer the signals from the electrodes to the patient monitor. The Trunk Cables have limited skin contact with the patient, while the Leadwires attached on the patient's chest have more continuous skin contact.

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The AIV cables use the same type of construction and have the same technological characteristics as the predicate devices. They use a medical grade PVC cable jacket with medical grade PVC overmolded connectors with an integral strain relief.

Intended Use:

These devices are intended to be used with various electrocardiograph recorders/monitors for both diagnostic and monitoring purposes. They are solely intended to be used between the electrode in contact with the patient's skin and the recording/monitoring device. This cabling facilitates the conduction of signals between the patient and the monitoring device. AIV cables are limited by the Indications for Use of the connected recording/monitoring device.

Comparison to Predicate Device:

	AIV	ConMed	GE Medical Systems
Intended Use	To conduct impulse signals from electrode to the patient monitor.	Same	Same
Patient Usage	Reusable.	Same	Same
Anatomical Sites	Attached to electrodes placed at standard specified locations on chest wall.	Same	Same
Design/Appearance	Cables with various connectors (monitor, trunk/leadwire, electrode grabber & snapper.	Same	Same
Type of Construction	Flexible, shielded, multi conductor electrical cable.	Same	Same
Connector Design	Trunk cable connectors are keyed to fit the appropriate monitors and snap and grabber for electrodes.	Same	Same
Cable Length	Various specified lengths.	Same	Same
Wire Colors	Snappers and grabbers color coded e.g. red, white, green, black, brown,	Same	Same
Wire Material	Braided shield, tin/copper with elastomer jacket.	Same	Same
Sterility	Used non-sterile.	Same	Same
Connector Retention Force	ANSI/AAMI EC53A-1998/(R)2001	Same	Same
Electrical Performance and Safety	ANSI/AAMI EC53-1995/(R)2001	Same	Same

Performance Data and Conclusions:

- AIV design is equivalent to predicate device design.
- Bench Testing demonstrates that the AIV devices perform as intended.
- The company has declared conformity to consensus standard ANSI/AAMI EC53-1995/(R)2001 and its attachment EC53A-1998/(R)2001 relating to Electrical/Safety/Mechanical
- These devices do not raise new issues of safety and effectiveness, nor do they alter the fundamental technology of the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 2 7 2007

American IV Products, Inc.
c/o Dr. John Taylor
Director of Engineering
7485 Shipley Ave.
Harmans, MD 21077

Re: K070232
Trade/Device Name:
Regulation Number: 21 CFR 870.2900
Regulation Name: Transducer and Electrode Patient Cable (Including Connector)
Regulatory Class: Class II
Product Code: DSA
Dated: January 19, 2007
Received: January 24, 2007

Dear Dr. Taylor:

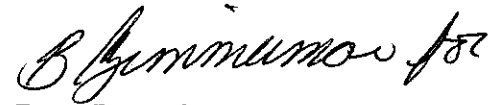
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 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) that do not require approval of a premarket approval application (PMA). 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 (PMA), 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 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 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), please contact the Office of Compliance at 240-276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K070232

Device Name: ECG Cables, Trunk and Patient Lead Wires

Indications For Use:

These devices are intended to be used with various electrocardiograph recorders/monitors for both diagnostic and monitoring purposes. They are solely intended to be used between the disposable electrodes (not manufactured by AIV) in contact with the patient's skin and the recording/monitoring device (not manufactured by AIV). These cables are used by qualified personnel in the field of Cardiology for diagnostic and monitoring purposes. AIV cables are limited by the Indications for Use of the connected recording/monitoring device. No other usage is intended for the trunk cables or leadwires.

AIV Part #	Predicate Part #	Predicate Manufacturer
EG11481	FSR1311	ConMed Trunk Cable
EG11482	FSR565	ConMed Trunk Cable
EG11479	FSR1303	ConMed Trunk Cable
EG11480	FSR1534	ConMed Trunk Cable
EG11478	FSR1390 FSR1590	ConMed Trunk Cable ConMed Trunk Cable
EG11477	FSR367	ConMed Trunk Cable
EG11483	FSR1370	ConMed Trunk Cable
EG11484	FSR1539	ConMed Trunk Cable
EG11476	D8338II D8538	ConMed Trunk Cable ConMed Trunk Cable
EG11475	2017003-001	GE Medical Systems Trunk Cable
EG11487	FSP24-003R DA24-03II 411203-001	ConMed Leadwire ConMed Leadwire GE Medical Systems Leadwire
EG11488	FSA24-003R DL24-03II 412682-001	ConMed Leadwire ConMed Leadwire GE Medical Systems Leadwire
EG11485	FSP24-005 ~~DA24-05~~ 411202-001	ConMed Leadwire ConMed Leadwire GE Medical Systems Leadwire

(Division Sign-Off)
Division of Cardiovascular Devices
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Indications for Use

EG11486	FSA24-005	ConMed Leadwire
	DL24-05	ConMed Leadwire
	412681-005	GE Medical Systems Leadwire

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number k070432