K102430
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4. 510(k) Summary

4.1 *General Information*

Submitter's Name:	Tyco Electronics Corporation
Address:	10025 S.W. Freeman Court Wilsonville, OR 97070
Establishment Registration:	3026961
Telephone Number:	(503) 673-5027
Fax Number:	(503) 685-9305
Contact Person:	Dennis M. Gilkey
Submission Preparation Date:	July 21, 2010

SEP 10 2010

4.2 *Device*

Trade/Proprietary Name:	Tyco Electronics Electrocardiograph (ECG) Leadwire Set
Common Name:	ECG Leadwire Set
Classification Name:	Patient transducer and electrode cable (including connector)
Product Code:	DSA
CFR Reference:	21 CFR 870.2900
Class:	II

4.3 *Predicate Device*

Common Name:	ECG Cables
Proprietary Name:	ECG Cables
Product Code:	DSA
510(k) Owner:	Philips Medical Systems (Andover, MA)
510(k) Number:	#K020531 (cleared March 20, 2002)

4.4 *Device Description*

Tyco Electronics Electrocardiograph (ECG) Leadwire Sets are intended for use with ECG monitors manufactured by Philips Medical Systems. Both the Philips and the Tyco Electronics groups of leadwire sets are designed specifically for compatibility with Philips ECG monitors and consist of insulated copper conductors with connectors on each cable end.

The term leadwire set includes ECG leadwires as well as the attached proximal and distal connectors. Leadwire sets are used to transfer signals originating from skin-mounted ECG electrodes (distal end) to a patient monitoring device (proximal end).

Tyco Electronics ECG Leadwire Sets are single-use devices within the meaning of that term as used by FDA – that is, they cannot be reprocessed and re-used. As described by FDA[1], a single-use device, also referred to as a disposable device, is not intended to be reprocessed (cleaned, disinfected/sterilized) and used on another patient.
All leadwire sets addressed within this 510(k) submission are produced in a configuration that is shielded against electromagnetic interference; they are single-use devices, not sterilizable and not reusable, intended for short-term use only (recommended use duration 7 days or less).

[1] Enforcement Priorities for Single-Use Devices Reprocessed by Third Parties and Hospitals; August 14, 2000

4.5 *Intended Use*

The Tyco Electronics ECG Leadwire Set is used to transmit signals from patient-connected electrodes or transducers to Philips electrocardiograph recorders/monitors for both diagnostic and monitoring purposes. Use is limited by the indications for use of the connected monitoring or diagnostic equipment.

Tyco Electronics Electrocardiograph (ECG) Leadwire Sets are single-use devices; they are supplied non-sterile and are not sterilizable or reusable. Tyco Electronics Electrocardiograph (ECG) Leadwire Sets are intended for short-term use only (recommended use duration 7 days or less), by trained operators in a medical environment.

4.6 *Product Comparison*

The table below provides a comparison between Tyco Electronics ECG Leadwire Set cables and the predicate ECG cables manufactured by Philips Medical Systems. The primary difference between the two products is that Tyco Electronics ECG Leadwire Sets are single-use devices whereas Philips leadwire sets are reusable.

Parameter	Tyco Electronics New Device	Philips Medical Systems Predicate Device
Intended Use	Transmit signals from patient-connected surface electrodes to Philips electrocardiograph recorders/monitors for both diagnostic and monitoring purposes.	Same
Sterility	Supplied non-sterile; cannot be sterilized or otherwise reprocessed	Supplied non-sterile; can be sterilized (no autoclave)
Reusability	Not reusable	Reusable
Anatomical Sites	Attached to electrodes placed at standard specified locations on chest wall and extremities	Same
Design/Appearance	Cables with "snap" configuration of ECG electrode connector (distal connector) and common "header" connection (proximal connector)	Same
Type of Construction	Flexible, shielded multi conductor electrical cable	Same
Distal Connector Design	1. Incorporates proprietary design to facilitate connection with Philips ECG monitors/recorders; 2. "Snap" electrode connectors are color coded – e.g., red, white, green, black, brown 3. Connector designations (LL, RL etc.) molded into plastic	1. Same 2. Same 3. Connector designations (LL, RL etc.) indicated by adhesive labels
Cable Length	1.0 m	1.0 m; 1.6 m
Wire Colors	White	Wires are color coded – e.g., red, white, green, black, brown
Wire Material	Shielded copper lead wire with polymer jacket	Same

Parameter	Tyco Electronics New Device	Philips Medical Systems Predicate Device
Proximal Connector Design	All-in-one common connector, fits only Philips ECG monitor/recorders; color-coded for use with ECG systems	Same

4.7 *Performance Data*

The Company has chosen to perform testing including but not necessarily limited to the external and/or recognized standards identified below:

- Medical electrical equipment IEC 60601-1:1998, including Amendments 1 (1991) and 2 (1995) and the national deviations described within UL 60601-1:2003 and ANSI/AAMI ES 60601-1:2005
- AAMI / ANSI EC13:2002/(R)2007, Cardiac monitors, heart rate meters, and alarms.
- AAMI / ANSI EC53:1995/(R) 2008, ECG cables and leadwires, including Amendment 1.
- AAMI / ANSI / ISO 10993-5:2009, Biological evaluation of medical devices -- Part 5: Tests for In Vitro cytotoxicity.
- ISO 10993-10:2002, Biological evaluation of medical devices - Part 10 and AMENDMENT 1: Tests for irritation and delayed-type hypersensitivity (including sensitization).

Compliance with the requirements of these standards will be achieved through verification testing, except in cases such as color and intrinsic design, where compliance will be achieved through product inspection. Testing against these standards is not complete at time of 510(k) filing. Testing will be conducted and will meet specified acceptance criteria prior to market release of the associated medical device.

Additional preference testing of product characteristics not related to safety and effectiveness and as specified by Tyco Electronics also will be performed.

4.8 *Conclusions*

Tyco Electronics ECG Leadwire Sets (the new device) serve as a conductor of electrical energy. The new device is substantially equivalent to electrocardiograph cable sets manufactured by Philips Medical Systems (Andover, MA), cleared as components of the Philips M1275B Component Compact Monitor (#K020531, clearance date March 20, 2002).

Product design and testing will be in conformance with FDA-recognized standards. Conformance with recognized standards ensures product design and function will raise no new issues related to safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Electronics Corporation
c/o Ms. Dawn Tibodeau
Responsible Third Party Official
TUV SUD America, Inc
1775 Old Hwy 8 NW, Ste 104
Wilsonville, OR 97070

SEP 10 2010

Re: K102430
Trade/Device Name: Tyco Electronics Electrocardiograph (ECG) Leadwire Set
Regulatory Number: 21 CFR 870.2900
Regulation Name: Transducer and Electrode Patient Cable (including connector)
Regulatory Class: II (two)
Product Code: DSA
Dated: August 21, 2010
Received: August 26, 2010

Dear Ms. Tibodeau:

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 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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 (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

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

Enclosure

K102430

3. Indications for Use Statement

510(k) Number (if known): K102430

Device Name: Tyco Electronics Electrocardiograph (ECG) Leadwire Set

SEP 10 2010

Indications for Use:

Tyco Electronics Electrocardiograph (ECG) Leadwire Sets are indicated for use in the monitoring of cardiac signals for both diagnostic and monitoring purposes. Use is limited by the indications for use of the connected monitoring or diagnostic equipment.

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K102430