K110287

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

PHILIPS

Philips ECG Leadwire Set

FEB 15 2011

Submitter's Name and Address

Submitter's Name:	Philips Medical Systems
Division:	Medical Consumers and Sensors
Address:	3000 Minuteman Road
City, State, and Zip:	Andover, MA 01810

Contact Person / Submission Correspondent

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Manufacturers' Information; Establishment Registration Number.

Establishment name:	Philips Medical Systems
Address:	3000 Minuteman Road Andover, MA 01810
Establishment Registration No.	1218950

New Device Details

Proprietary or Trade Name:	Philips ECG Leadwire Set
Common Name:	ECG Leadwire Set
Device Class:	Class II
Device Procode:	DSA
Device CFR:	21 CFR 870.2900
Classification Panel:	Cardiovascular
Classification Name:	Patient transducer and electrode cable (including connector).

K110287

Predicate Device Details

510(k) Number	K102430 (cleared on September 10, 2010)
Proprietary or Trade Name:	Tyco Electronics Electrocardiograph (ECG) Leadwire Set
Common Name:	ECG Leadwire Set
Device Class:	Class II
Device Procode:	DSA
Device CFR:	21 CFR 870.2900
Classification Panel:	Cardiovascular
Classification Name:	Patient transducer and electrode cable (including connector).

Device Description

The Philips ECG Leadwire Set is a single patient electrode cable system used to transfer signals from patient electrodes to various electrocardiograph recorders and monitors. The system is designed to provide a family of lead wires that will link the patient and the compatible patient trunk cable system.

Intended Use

Philips Single-Patient-Use Disposable ECG Leadsets are intended for use only by trained healthcare professionals for measurement of a patient's ECG for both diagnostic and monitoring purposes. Use is limited by the indications for use of the connected monitoring or diagnostic equipment. These Philips leadsets are intended for short-term use only (an average patient stay of 5 days).

Product Comparison

The new device has equivalent technological characteristics related to safety and effectiveness as the predicate device.

The primary difference between the new device and the predicate is that Philips ECG Leadwire Set utilizes a grabber connector and the predicate utilizes a snap connector to fasten to the electrode.

The indications for use for the new device is identical to the predicate. Though the leadsets are used to transfer signals from patient electrodes, actual use is limited by the indications for use of the connected monitoring or diagnostic equipment.

The new device and the predicate cannot be sterilized or otherwise reprocessed for reuse; they are intended to be used only with one patient then discarded.

The following table provides a comparison between the Philips ECG Leadwire Set cables and the predicate Tyco Electronics ECG Leadwire Set cables.

K110287

Specification	Philips ECG Leadwire Set (New Device)	Tyco Electronics ECG Leadwire Set (Predicate) K102430	Comparison
Indications for Use	Philips ECG leadsets 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.	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.	Same
Sterility	Supplied non-sterile; cannot be sterilized or otherwise reprocessed	Supplied non-sterile; cannot be sterilized or otherwise reprocessed	Same
Reusability	Not reusable	Not reusable	Same
Anatomical Sites	Attached to electrodes placed at standard specified locations on chest wall and extremities	Attached to electrodes placed at standard specified locations on chest wall and extremities	Same
Design / Appearance	Cables with "grabber" configuration of ECG electrode connector (distal connector) and common "header" connection (proximal connector)	Cables with "snap" configuration of ECG electrode connector (distal connector) and common "header" connection (proximal connector)	Substantially Equivalent
Type of Construction	Flexible shielded multi conductor electrical cable	Flexible shielded multi conductor electrical cable	Same
Distal Connector Design	"Grabber" electrode connectors are color coded (red, white, green, black, brown) Connector designations (LL,RL etc.) molded into plastic	"Snap" electrode connectors are color coded (red, white, green, black, brown) Connector designations (LL,RL etc.) molded into plastic	Substantially Equivalent Same
Cable Length	1.0 m and 0.85 m	1.0 m	Substantially Equivalent
Wire Colors	White	White	Same
Leadwire Construction	Ribbonized leads with individual coax shields	Shielded copper lead wire with polymer jacket	Substantially Equivalent
Proximal Connector Design	All-in-one common connector, fits only Philips ECG monitor/recorders; color coded for use with ECG systems	All-in-one common connector, fits only Philips ECG monitor/recorders; color coded for use with ECG systems	Same

Performance Data

Testing includes but is not necessarily limited to the 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 EC 13:2002/(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 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 Philips Medical Systems will also be performed.

Conclusions

The Philips ECG Leadwire Sets (the new device) serve as a conductor of electrical energy. The new devices are substantially equivalent to predicate.

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.

Based on similarity in technology, characteristics and indications for use as the predicate, the Philips ECG Leadwire Sets are substantially equivalent.

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

Philips Medical Systems
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TUV SUD America
1775 Old Highway 8
New Brighton, MN 55112-1891

FEB 15 2011

Re: K110287
Trade/Device Name: Philips ECG Leadwire Set
Regulation Number: 21 CFR 870.2900
Regulation Name: Patient Transducer and Electrode Cable (Including Connector)
Regulatory Class: Class II
Product Code: DSA
Dated: January 28, 2011
Received: January 31, 2011

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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

4.0 Indications for Use Statement

PHILIPS

510(k) Number: K110287

Device Name: **Philips ECG Leadwire Set**

Indications for Use:

Philips ECG leadsets 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 (21 CFR 801 Subpart D)	X	AND/OR	Over-The-Counter Use (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K110287