510(k) Summary

K101660

A) SUBMITTED BY : Kepler MedTec
223 Avenue D
Willston, VT 05495
(facility registration # 3008160705)

CONTACT: MEDIcept Inc.
200 Homer Ave
Ashland, MA 01721
F. David Rothkopf
508-231-8842
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AUG 11 2010

B) DEVICE NAME: **Single Patient Use ECG Lead Wire Set**

COMMON NAME: ECG Patient Cable

DEVICE CLASS: Class II

PRODUCT CODE: DSA, 870.2900 Cable, transducer and electrode, patient (including connector)

C) PREDICATES:

K980582 Marquette Medical Systems: ECG Lead Wire and Cable System
Intended use: Multi-Link Cable and Lead Wire Systems are reusable electrode cable system used to transmit signals from patient electrodes to various electrocardiograph recorders/monitors fro both diagnostic and monitoring purposes. Multi-Link Cable and Lead Wire Systems are limited to indications for use of the connected monitoring or diagnostic equipment. Such equipment is commonly located in hospitals, doctor's offices, and emergency vehicles, as well as in home use.

K082851 GE Medical Systems: Multi-Link Cable and Lead Wire System
Intended use: Multi-Link Cable and Lead Wire Systems are electrocardiograph cable systems used to transmit signals from patient surface electrodes to various electrocardiograph recorders/monitors for both diagnostic and monitoring purposes. Use is limited by the indications for use of the connected monitoring or diagnostic equipment. Multi-Link Cable and Lead Wire Systems are intended to be used by trained operators in a medical professional environment.

D) DEVICE DESCRIPTION:

The Single Patient Use ECG Lead Wire is a single patient, electrode cable system used to transmit signals from patient surface electrodes to various electrocardiograph recorders/monitors for both diagnostic and monitoring purposes. This type of device is common to both industry and to most medical establishments. The system is designed to provide a family of lead wires that will link the patient and the compatible patient trunk cable system.

E) INTENDED USE:

The Single Patient Use ECG Lead Wire is an electrode cable systems used to transmit signals from patient electrodes to various electrocardiograph recorders / monitors for both diagnostic and monitoring purposes. Use is limited by the indications for use of the connected monitoring or diagnostic equipment. The Single Patient Use ECG Lead Wire set is intended to be used by trained operators in a medical professional's environment.

F) COMPARISON TO PREDICATE DEVICES(s):

Device Features	**Single Patient Use ECG Lead Wire Set**	**Predicate** K980582 Marquette Medical Systems: ECG Lead Wire and Cable System	**Predicate** K082851 GE Medical Systems: Multi-Link Cable and Lead Wire System
Intended Use	Transmit signals from patient electrodes to various electrocardiograph recorders / monitors for both diagnostic and monitoring purposes	Same	Same
Patient Usage	Reusable	Reusable	Reusable
Anatomical Sites	Attached to electrodes placed at standard specified locations on the chest wall	Same	Same
Sterilization	Provided non-sterile	Provided non-sterile	Provided non-sterile
Wire Material/ Connector Design Construction	Flexible, Shielded multi-connector electrical cable keyed to fit specific monitors and snap for electrodes	Same but additionally may use Grabber and Banana electrode termination configuration	Same but additionally may use Grabber, Banana, or Mactrode electrode termination configuration
Instrument interface connector	Compatible to MultiLink yoke design	Compatible to MultiLink yoke design	Compatible to MultiLink yoke design
Connector Retention Force	ANSI/AMMI EC 53A	Same	Same
Electrical Performance	ANSI/AMMI EC 53A	Same	Same

The Single Patient Use ECG Lead Wire has a similar intended use, target population, clinical setting, and technology as its predicate devices.

G) STANDARDS MET:

- ANSI/AMMI EC53-1995 (R)2001, R(2008) *ECG Cables and Leadwires* (except 4.3.1)
- ANSI/AAMI EC13:2002 *Cardiac monitors, heart rate meters and alarms* (only product markings, chapter 4.1.1.5)
- 21 CFR 898: *Guidance Document on the Performance Standard for Electrode Lead Wires and Patient Cables, May 11, 1998*
  IEC 601-1 (1998), *"Medical Electrical Equipment - Part 1: General Requirements for Safety,"* (R)1995 subclause 56.3(c)
- EN/ISO 10993-1:2003 *Biological evaluation of Medical Devices, Part 1: Guidance on selection of tests*

H) CONCLUSION:

Kepler MedTec believes that the Single Patient Use ECG Lead Wire Set is as safe and effective and is substantially equivalent to the predicate devices based on intended usage, technology comparison and system performance.

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

AUG 1 1 2010

Kepler MedTec
c/o Mr. F. David Rothkopf
MEDIcept, Inc.
200 Homer Ave.
Ashland, MA 01721

Re: K101660
Trade/Device Name: Single Patient Use ECG Lead Wire Set
Regulatory Number: 21 CFR 870.2900
Regulation Name: Patient Transducer and Electrode Cable (Including Connector)
Regulatory Class: Class II (Two)
Product Code: DSA
Dated: June 8, 2010
Received: June 14, 2010

Dear Mr. F. David Rothkopf:

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.

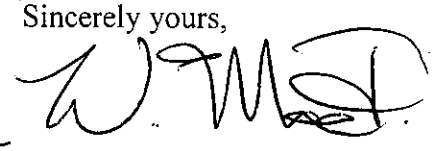
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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

Indications for Use Form

510(k) Number (if known): K101660

Device Name: Single Patient Use ECG Patient Lead Wire Set

AUG 11 2010

Indications for Use:

The Kepler MedTec Single Patient Use ECG Lead Wire is a electrode cable system used to transmit signals from patient electrodes to various electrocardiograph recorders / monitors for both diagnostic and monitoring purposes. Use is limited by the indications for use of the connected monitoring or diagnostic equipment. The Single Patient Use ECG Lead Wire Set is intended to be used by trained operators in a medical professional's environment.

Prescription Use X 21CFR 801, Subpart D **OR** Over-the-Counter Use _ 21CFR 801.109

(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

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