K093172

JAN 20 2010

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Section 5 – 510(k) Summary

Submitter:	Dynacardia, Inc. 1330 Mountain View Circle, Azusa, *California* 91702
Contact Person:	Wei-min Brian Chiu, Ph.D., President Phone: (626) 610-1896; Fax: (626) 610-1897 Email: brianchiu@dynacardia.com
Date Prepared:	August 22, 2009
Trade Name:	Quantitative Electrocardiographic Detector (QED 1000)
Classification:	Class II Electrocardiograph 21 CFR §870.2340
Product Code:	DPS
Predicate Device(s):	The subject device is equivalent to the following devices: o K080999: "Philips PageWriter"; Philips Medical Systems o K073625: "MAC 5500"; GE Healthcare Systems
Device Description:	The Quantitative Electocardiographic Detector (QED) is a 12-lead resting electrocardiograph. It is a reusable device for acquiring, displaying, and storing the 12-lead electrocardiogram.
Intended Use:	The intended use of the QED 1000 is to record 12-lead ECG signals from adult patients from body surface ECG electrodes. This device can acquire, display, record, and store these ECG signals for review by the user. The QED 1000 is intended to be used in healthcare facilities by trained healthcare professionals. A qualified physician must over-read all computer-generated tracings. The QED 1000 is designed for use by a qualified physician to evaluate the electrocardiogram of adult patients as part of clinical diagnosis.
Functional and Safety Testing:	To verify that device design met its functional and performance requirements, representative sample of the device underwent electromagnetic compliance and electrocardiograph standard testing in accordance with EN 60601-1-2: 2007 and ANSI/AAMI EC 11: 1999/(R) 2001.
Conclusion:	Dynacardia, Inc. considers the QED 1000 to be equivalent to the predicate devices listed above. This conclusion is based upon the devices' similarities in principles of operation, technology, and indications for use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

Dynacardia, Inc.
c/o Mr. Morten Simon Christensen
Underwriters Laboratories Inc.
455 E. Trimble Road
San Jose, CA 95131

JAN 20 2010

Re: K093172
Trade/Device Name: Quantitative Electrocardiographic Detector (QED 1000)
Regulatory Number: 21 CFR 870.2340
Regulation Name: Electrocardiograph
Regulatory Class: Class II (Two)
Product Code: DPS
Dated: January 4, 2010
Received: January 5, 2010

Dear Mr. Christensen:

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

Section 4 – Indications for Use Statement

Device Name: Quantitative Electrocardiographic Detector (QED 1000)

Intended Use:

The intended use of the QED 1000 is to record 12-lead ECG signals from adult patients from body surface ECG electrodes. This device can acquire, display, record, and store these ECG signals for review by the user.

The QED 1000 is intended to be used in healthcare facilities by trained healthcare professionals. A qualified physician must over-read all computer-generated tracings.

The QED 1000 is designed for use by a qualified physician to evaluate the electrocardiogram of adult patients as part of clinical diagnosis.

Prescription Use ___X___ (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 IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number ~~K093911~~ K093172

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