K108640 p1/2

5. 510(k) Summary

MAR 2 2 2011

Midmark Diagnostics Group

Submitter: Midmark Diagnostics Group

Trade Names: Midmark IQecg

Common Name: Electrocardiograph

Classification Name: Electrocardiograph

Classification Regulation: 21 CFR 870.2340

Product Code: DPS

Device Description:
The Midmark IQecg is a PC based 12-lead resting diagnostic electrocardiograph with interpretation and data storage capabilities. Together with the Midmark IQmanager software running on Microsoft Windows operating systems, the IQecg device can acquire 12-lead ECG (electrocardiogram) data, generate ECG measurement and interpretation results, provide review/edit functions to modify the measurement and interpretation results, store the ECG data and report in a database, archive the ECG reports for future reference and share the ECG reports with other physicians via network or email. The IQecg can also be connected to servers and electronic medical records.

Technology Comparison:
The Midmark IQecg utilizes the same or similar technology for each parameter as utilized by the predicate device PC-ECG (K955023). This 510(k) is primarily being submitted for these changes:

Technological Characteristics	Midmark IQecg	PC-ECG (K955023)
Frequency response bandwidth	0.05Hz - 150Hz	0.05Hz-110 Hz
ECG signal sampling rate	500 samples/second	250 samples/second
QT Correction (QTc) Measurement	User can select up to 2 from 4 formulas for QTc measurement: Hodges, Bazett, Framingham, or Fridericia. Default QTc value is Hodges formula.	Calculated using Hodges formula

Intended Use:
The Midmark IQecg is indicated for use, under the supervision of a Physician, to obtain electrocardiograms from the adult and pediatric human body surface. The process of taking an electrocardiogram is non-invasive, painless, without direct risk to the patient and is reproducible.

Performance Testing:
The Midmark IQecg was tested in accordance with requirements and procedures, and test results indicated that the device complies with the predetermined requirements.

Conclusion:
Based upon a comparison of devices and performance testing results, the Midmark IQecg is as safe and performs as effectively as the predicate device.

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

Brentwood Medical Technology Corp.
Midmark Diagnostics Group
c/o Mr. Greg Holland
Regulatory Regulatory Specialists, Inc.
3722 Ave. Sausalito
Irvine, CA 92606

MAR 2 2 2011

Re: K103640
Trade/Device Name: Midmark IQecg Electrocardiograph
Regulation Number: 21 CFR 870.2430
Regulation Name: Electrocardiograph
Regulatory Class: Class II (two)
Product Code: DPS
Dated: December 7, 2010
Received: December 13, 2010

Dear Mr. Holland:

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,

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

Enclosure

4. Indications for Use Statement

Indications for Use

510(k) Number: K103640

Device Name: Midmark IQecg

Indications for Use:

The Midmark IQecg is indicated for use, under the supervision of a Physician, to obtain electrocardiograms from the adult and pediatric human body surface. The process of taking an electrocardiogram is non-invasive, painless, without direct risk to the patient and is reproducible.

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

for B Zuckerman

(Division Sign-Off) 3/22/2011
Division of Cardiovascular Devices
510(k) Number K103640