Energy-Lab Technologies GmbH
Vicardio Electrocardiograph
510(k) Submission

510(k) Summary

(1) Submitter Information
   Name: Energy-Lab Technologies GmbH
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   info@vicardio.com

   Contact Person: Dr. George Myers
   Medsys Inc.
   377 Rt. 17 S
   Hasbrouck Heights, NJ 07604
   201-727-1703
   Fax 201-727-1708
   Email medsyscons@yahoo.com
   Date Prepared: July 8, 2008

(2) Name of Device:
   Trade Name: vicardio 12b
   Common Name: Electrocardiograph
   Classification Name: Electrocardiograph

(3) Equivalent legally-marketed devices:
   Spacelabs CardioDirect K024283
   Spacelabs CardioCollect K013367

(4) Description
   The vicardio is a digital, PC-based electrocardiograph with a special isolation amplifier between the patient and the computer.
(5) Intended Use
The vicardio is indicated for the recording of resting electrocardiograms (ECG), and for making measurements on the electrocardiograms, by a physician or under the direction of a physician.

(6) Technological characteristics
The vicardio is a digital electrocardiograph to be used with the purchaser’s own PC.

(b) Performance data
(1) Non-clinical tests
   The software has been extensively validated and tested. The device will have passed AAMI/ANSI EC11 tests.

(2) Clinical tests
   Clinical tests were not required.

(3) Conclusions
   The vicardio is equivalent in safety and efficacy to the legally marketed predicate devices.
Energy-Lab Technologies, GmbH  
c/o Mr. Robert Mosenkis  
President  
Citech  
5200 Butler Pike  
Plymouth Meeting, PA 19462

Re: K082380  
Trade/Device Name: Vicardio 12B  
Regulation Number: 21 CFR 870.2340  
Regulation Name: Electrocardiograph  
Regulatory Class: Class II (special controls)  
Product Code: DPS  
Dated: November 14, 2008  
Received: November 17, 2008

Dear Mr. Mosenkis:

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 such 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); 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. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometrics' (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

[Signature]

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

Enclosure
Indications for Use

510(k) Number (if known): \textbf{K082380}

Device Name: vicardio 12b

Indications for Use:

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