

K082380
page 1/2

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

DEC 03 2008

510(k) Summary

(1) Submitter Information

Name: Energy-Lab Technologies GmbH
Address: Energy-Lab Technologies GmbH
Burchardstraße 21
20095 Hamburg / Germany

Tel.: +49-(0)40 - 30 37 23 30

Fax: +49-(0)40 - 30 37 23 50

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.

K082380
page 2/2

(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.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 03 2008

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.

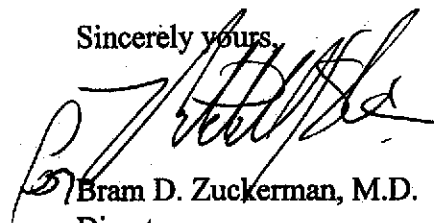
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish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



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): K082380

Device Name: vicardio 12b

Indications for Use:

The vicardio12b 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.

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 OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)


for BZuckerman
12/2/08
(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K082380

Page 1 of 1