K082709

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5. 510(k) Summary

Date: 15 September 2008

DEC 29 2008

Applicant:

Vicor Technologies, Inc.
2300 NW corporate Boulevard,
Suite 123
Boca Raton, FL 33431

Tel: (561) 995-7313
Fax: (800) 244-5197

Contact:

Dr. Jules T. Mitchel
Target Health Inc.
261 Madison Avenue,
24th Floor
New York, NY 10016

Tel: (212) 681-2100
Fax: (212) 682-2105
julesmitchel@targethealth.com

K032720
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Device name	Vicor PD2i Analyzer
Trade Name	Vicor PD2i Analyzer
Common Name	Electrocardiograph
Classification Name	Electrocardiograph (21 CFR 870.2340, Product Code DPS)
Predicate Device	The Portable ANSiscope ECG Monitoring System K071168
Description of Device	The Vicor PD2i Analyzer is a software algorithm for recording heart rate variability (HRV) using the Point Correlation Dimension Algorithm (PD2i).
Intended Use	The Vicor PD2i Analyzer is intended to display and analyze electrocardiographic information and to measure heart rate variability (HRV). These and other measurements are not intended for any specific clinical diagnosis. The clinical significance of HRV and other parameters must be determined by the physician.
Comparison to Predicate Device	The Vicor PD2i Analyzer has the same intended use as the legally marketed predicate device. The Vicor PD2i Analyzer is intended for use in heart rate variability (HRV) measurements.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 29 2008

Vicor Technologies, Inc.
c/o Jules T. Mitchel, MBA, Ph.D.
President, Target Health, Inc.
261 Madison Avenue, 24th Floor
New York, NY 10016

Re: K082709
Trade/Device Name: Vicor PD2i Analyzer
Regulation Number: 21 CFR 870.2340
Regulation Name: Electrocardiograph
Regulatory Class: Class II (two)
Product Code: DPS
Dated: December 11, 2008
Received: December 12, 2008

Dear Dr. Mitchel:

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,

M. J. Hillebrenner

for 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

510(k) Number (if known): K082709

Device Name: Vicor PD2i Analyzer

Indications for Use:

The Vicor PD2i Analyzer is intended to display and analyze electrocardiographic information and to measure heart rate variability (HRV). These and other measurements are not intended for any specific clinical diagnosis. The clinical significance of HRV and other parameters must be determined by the physician.

Prescription Use __x__ AND/OR Over-The-Counter Use ____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

Concurrence of CDRH, Office of Device Evaluation (ODE)

M.J. Hillebrenner

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K082709