K101867 p 1/3

510(k) Summary

APR 1 4 2011

1.1 Applicant and Contact Information

Date		30 March 2011
Applicant		Vicor Technologies, Inc. 2300 NW Corporate Boulevard, Suite 123 Boca Raton, FL 33431
Contact Person	Primary	Dr. Glen Park Sr Director, Clinical and Regulatory Affairs Target Health Inc. 261 Madison Avenue, 24th Floor New York, NY 10016 Tel: (212) 681-2032 Fax: (212) 682-2105 Gpark@targethealth.com
	Secondary	David H. Fater Vicor Technologies, Inc. 2300 NW Corporate Boulevard, Suite 123 Boca Raton, FL 33431 Tel: (561) 995-7313 Fax: (800) 244-5197 dfater@vicortech.com

1.2 Basic Device Identification

Device Name	Vicor PD2i Analyzer		
Device Proprietary Name	Vicor PD2i Analyzer		
Common/Usual Name	Programmable Diagnostic Computer		
Classification Names / Numbers and Code	**21 CFR**	**Classification Name**	**Code**
	870.2340	Electrocardiograph	DPS
Regulatory Class	II		
Prescription Status	Prescription Device		
Device / Classification Panel	Cardiovascular		
Predicate Device	Vicor PD2i Analyzer		K082709
Performance Standards	The Vicor PD2i Analyzer complies with voluntary standards. The following quality assurance measures were applied to the development of the system: • Level of Concern and Hazard Analysis • User Requirements • Software Requirement Specification • Software Design Specification • Detailed Software Design Specification • Software Development • IQ/OQ/PQ • IQ/OQ/PQ RESULTS • Software Release		
Technology	The Vicor PD2i Analyzer employs the same functional technology as the predicate device. This 510(k) notification presents changes to the user interface of the PD2i Analyzer software without change in the PD2i algorithm. Data in this submission demonstrate that these technological characteristics do not raise new questions of safety and performance.		
Description of Device	The Vicor PD2i Analyzer is a software algorithm for measuring 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) at rest and in response to controlled exercise and paced respiration in patients undergoing cardiovascular disease testing. The results are to be interpreted by a qualified healthcare		

	practitioner. 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	**Similarities**	**Differences**
	The software algorithm for calculating the HRV is unchanged.	ECG data is transmitted to a central server for calculating and reporting the HRV values. The device displays blood pressure data from an approved noninvasive blood pressure measuring device. The device displays the Ewing ratio in addition to the PD2i score.
Conclusion	The modifications in the Vicor PD2i Analyzer as stated above do not change the intended use. The information submitted in this application regarding the changes in technology does not raise new questions of safety and effectiveness and demonstrates that the device is as safe and effective as the legally marketed 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

Vicor Technologies, Inc.
c/o Glen D. Park PharmD
Sr. Director, Clinical and Regulatory Affairs
Target Health, Inc.
261 Madison Avenue, 24th Floor
New York, NY 10016

APR 14 2011

Re: K101867
Vicor PD2i Analyzer
Regulation Number: 21 CFR 870.2340
Regulation Name: Electrocardiograph
Regulatory Class: Class II
Product Code: DPS
Dated: March 29, 2011
Received: March 31, 2011

Dear Dr. Park:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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

Indications for Use

510(k) Number: K101867

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) at rest and in response to controlled exercise and paced respiration in patients undergoing cardiovascular disease testing. The results are to be interpreted by a qualified healthcare practitioner. 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)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K101867