3 510(k) Summary

JUN 27 2008

Date: 5/23/08

Submitter: Medical Predictive Science Corporation
2246 Ivy Rd, Suite 17
Charlottesville, VA 22903

Contact: William E King
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Trade Name: HeRO Version 2.0
Common Name: HRV Analysis System

Classification Name: Electrocardiograph
Classification Number: 21CFR 870.2340 74DPS, Class II

Predicate Device: K021230 (HeRO)

Device Description: HeRO Version 2.0 is comprised of off-the-shelf Personal Computers (PC's) and special-purpose hardware capable of acquiring, storing, analyzing, and reporting ECG data from the cardiac monitoring devices. Data is acquired on a special-purpose Data Acquisition Device (DAD). It is stored and analyzed on a server, also called the Central Monitoring Station (CMS), located in a data closet or other suitable location. Results of the analyses are reported on a viewing station, or Remote Monitoring Station (RMS). The analysis algorithms identify Heart Rate Variability (HRV) patterns that reflect transient decelerations and/or reduced baseline variability.

Intended Use:	HeRO is intended to acquire, store, analyze, and report on ECG data collected from infants. HeRO is intended to be used under the direct supervision of a licensed health care practitioner in a hospital neonatal or pediatric ICU environment. HeRO is intended to be used for the analysis of the variability in RR intervals (heart rate) and to report measurements of the variability of heart rate data (HRV). The HRV measurements reported by HeRO are specialized in nature, and intended to identify periods of transient decelerations and/or reduced baseline variability in the heart rate. HeRO is intended to provide only specialized HRV measurements and is not intended to produce any interpretation of those measurements or any kind of diagnosis. The specialized HRV measurements produced by HeRO have not been approved by the FDA for any specific clinical diagnosis. HeRO acquires data from a user-supplied ECG monitor, and requires a user-supplied local area network.
Technology:	Microprocessor based system.
Test Summary:	HeRO Version 2.0 was developed and is manufactured in accordance with 21CFR820 Quality System Regulations. The HeRO system has been third-party tested in accordance with UL 60601-1 and IEC 60601-1-2.
Conclusion:	HeRO Version 2.0 has an identical intended use as the predicate (unmodified) device. HeRO Version 2.0 raises no new questions of safety or efficacy when compared with the predicate device. Therefore, HeRO Version 2.0 is judged substantially equivalent to HeRO.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 27 2008

Medical Predictive Science Corporation
c/o Mr. William E. King
CEO
2246 Ivy Rd, Suite 17
Charlottesville, VA 22903

Re: K081473
Trade/Device Name: HeRO Version 2.0
Regulation Number: 21 CFR 870.2340
Regulation Name: Electrocardiograph
Regulatory Class: Class II
Product Code: DPS
Dated: May 23, 2008
Received: May 27, 2008

Dear Mr. King:

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.

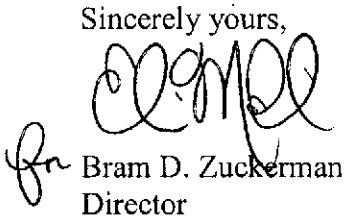
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish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



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

Enclosure

2 Indications for Use Statement

510(k) Number (if known): K081473
Device Name: HeRO

Indications for Use:

HeRO is intended to acquire, store, analyze, and report on ECG data collected from infants. HeRO is intended to be used under the direct supervision of a licensed health care practitioner in a hospital neonatal or pediatric ICU environment.

HeRO is intended to be used for the analysis of the variability in RR intervals (heart rate) and to report measurements of the variability of heart rate data (HRV). The HRV measurements reported by HeRO are specialized in nature, and intended to identify periods of transient decelerations and/or reduced baseline variability in the heart rate.

HeRO is intended to provide only specialized HRV measurements and is not intended to produce any interpretation of those measurements or any kind of diagnosis.

The specialized HRV measurements produced by HeRO have not been approved by the FDA for any specific clinical diagnosis.

HeRO acquires data from a user-supplied ECG monitor, and requires a user-supplied local area network.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NECESSARY)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use ____
(Per 21 CFR 801.109) (Optional Format 1-2-96)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K081473