February 28, 2018

Medical Predictive Science Corporation
William King
Chief Executive Officer
2246 Ivy Road, Suite 17
Charlottesville, Virginia 22903

Re: K180242
Trade/Device Name: HeRO Symphony, HeRO ES, HeRO solo/duet
Regulation Number: 21 CFR 870.2340
Regulation Name: Electrocardiograph
Regulatory Class: Class II
Product Code: DPS
Dated: January 26, 2018
Received: January 29, 2018

Dear William 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. 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.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

for

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

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K180242

Device Name
HeRO Symphony, HeRO solo/duet, HeRO ES

Indications for Use *(Describe)*
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.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

Section 08: 510(k) Summary

1. Applicant

Owner Name	Medical Predictive Science Corporation
Owner Address	2246 Ivy Rd, Suite 17 Charlottesville, VA 22903 Tel: (434) 220 0714 Fax: (240) 220 6098
Contact	William E King, CEO (434) 220 0714 x113 wking@heroscore.com
Date of Preparation	1/25/18

2. Device

Common Name	Electrocardiograph, HRV Analysis System
Trade Names	HeRO Symphony HeRO solo/duet HeRO ES
Classification Number	21 CFR 870.2340
Classification & Product Code	Class II, DPS

3. Predicate

Predicate Device	HeRO 3.0
Predicate Device Manufacturer	Medical Predictive Science Corporation
Predicate Device Common Name	Electrocardiograph, HRV Analysis System
Predicate Device Classification Number	21 CFR 870.2340
Predicate Device Classification & Product Code	Class II, DPS
Predicate Device Premarket Notification #	K111601

4. Description of Devices

HeRO Symphony, HeRO solo/duet, and HeRO ES are 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 real-time network. Data is acquired either on a special-purpose Data Acquisition Device (DAD) or via the physiological monitoring network. It is stored and analyzed on a HeRO Server or physiological monitor. Results of the analyses are reported on one or more Viewing Stations. The analysis algorithms identify Heart Rate Variability (HRV) patterns that reflect transient decelerations and/or reduced baseline variability.

5. Indications for Use

HeRO is intended to acquire, store, analyze, and report on ECG data collected from infants. HeRO is intended to be used by trained operators 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.

6. Summary of Technological Characteristics

HeRO Symphony, HeRO solo/duet, and HeRO ES share the same software as HeRO 3.0, and are identical in technological characteristics. HeRO Symphony is the marketing name for network-based implementations of HeRO, with a separate server and viewing stations. HeRO solo and duet implement the server and viewing station functionality on a single medical-grade PC for one or two beds. HeRO ES implements HeRO on the integrated PC (iPC) of a Philips MX700 or MX800 monitor.

New labeling has been created that is specific to each of these three embodiments. The new instructions for use differ from the previously cleared device in updated (and specific) screenshots, availability of electronic copies of the labeling, references and annotations to new journal articles supporting the intended use[1-6], simplification of the user interface particularly related to admission, transfer, and discharge, and general edits for clarification.

7. Summary of Supporting Data

HeRO Symphony, HeRO solo/duet, and HeRO ES were developed and are manufactured in accordance with 31 CFR 820 Quality System Regulations. HeRO specific hardware has been third-party tested in accordance with IEC 60601-1 and IEC 60601-1-2. HeRO Symphony, HeRO solo/duet, and HeRO ES performance matches the product specifications.

The nonclinical testing that is part of the processes described above demonstrate the HeRO Symphony, HeRO solo/duet, and HeRO ES are as safe, as effective, and perform as well as or better than HeRO 3.0.

8. References

[1] Moorman JR, Delos JB, Flower AA, Cao H, Kovatchev BP, Richman JS, Lake DE. Cardiovascular oscillations at the bedside: early diagnosis of neonatal sepsis using heart rate characteristics. Physiological Measures, 2011.

[2] Addison K, Griffin MP, Moorman JR, Lake DE, O'Shea TM. Heart rate characteristics and neurodevelopmental outcome in very low birth weight infants. *J Perinatol*. 29:750-6, 2009.

[3] Stone ML, Tatum PM, Weitkamp JH, Mukherjee AB, Attridge J, McGahren ED, Rodgers BM, Lake DE, Moorman JR, Fairchild KD. Abnormal heart rate characteristics before clinical diagnosis of necrotizing enterocolitis. *J Perinatol*. (2013) May 30.

[4] Vergales BD, Zanelli SA, Matsumoto JA, Goodkin HP, Lake DE, Moorman JR, Fairchild KD. Depressed Heart Rate Variability is Associated with Abnormal EEG, MRI, and Death in Neonates with Hypoxic Ischemic Encephalopathy. *Am J Perinatol*. (2013) Dec 17.

[5] Moorman JR, Carlo WA, Kattwinkel J, Schelonka RL, Porcelli PJ, Navarrete CT, Bancalari E, Aschner JL, Walker MW, Perez JA, Palmer C, Wagner DP, Stukenborg GJ, Lake DE, O'Shea TM. Mortality benefit of heart rate characteristics monitoring in very low birth weight infants: a randomized trial. *J Pediatr* 2011.

[6] Heart rate characteristics: novel physiomarkers to predict neonatal infection and death. Griffin MP, Lake DE, Bissonette EA, Harrell FE, O'Shea TM, Moorman JR. Pediatrics 116:1070-4, 2005.