DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

May 27, 2016

Ivy Biomedical Systems, Inc.
Nicole Bush
Director of Regulatory
11 Business Park Drive
Branford, Connecticut 06405

Re: K151781
Trade/Device Name: 7810 Cardiac and Respiratory Synchronization Monitor
Regulation Number: 21 CFR 870.2300
Regulation Name: Cardiac Monitor (Including Cardiotachometer and Rate Alarm)
Regulatory Class: Class II
Product Code: DRT
Dated: April 18, 2016
Received: April 19, 2016

Dear Nicole Bush:

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 contact the Division of Industry and Consumer Education 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. 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.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education 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,

Shawn W. Forrest -S
2016.05.27 15:18:37 -04'00'

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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K151781

Device Name
7810 Cardiac and Respiratory Synchronization Monitor

Indications for Use *(Describe)*

The Ivy Biomedical Model 7810 ("7810") is a basic cardiac monitor used to provide cardiac and respiratory trigger pulse outputs used by third-party systems that require ECG or respiratory synchronization. Cardiac and respiratory synchronization is commonly used in diagnostic imaging modalities (i.e., nuclear medicine, computed axial (CAT), or positron emission (PET) tomography) or other applications requiring such synchronization.

The 7810 is intended for use in pediatric and adult patients undergoing diagnostic imaging and related procedures in inpatient and outpatient centers under the supervision of licensed healthcare professionals.

The product is not intended for use as a life support, home monitoring, or magnetic resonance imaging (MRI) modality.

Patient Population
The Model 7000 Series Cardiac Trigger Monitor is intended to perform ECG monitoring and R-wave pulse detection on adult, geriatric, pediatric and neonatal patients. R-Wave synchronization is typically used for gating nuclear scanners, CT scanners, or other imaging devices.

Contraindications
The Model 7000 Series is limited to use by trained and qualified medical professionals. This device is not intended for use as life support equipment or for performing cardiac diagnostics. The product is not intended for use in home care monitoring or for use in an MRI environment.

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.

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