DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

January 16, 2015

Decisio Health, Inc.
c/o Ronald Warren
Regulatory Consultant
Experien Group, LLC
755 N. Mathilda Avenue, Suite 100
Sunnyvale, California 94085

Re: K142106
Trade/Device Name: Decisio Health Patient Dashboard
Regulation Number: 21 CFR 870.2300
Regulation Name: Cardiac Monitor (Including Cardiotachometer And Rate Alarm)
Regulatory Class: Class II
Product Code: MWI
Dated: December 18, 2014
Received: December 19, 2014

Dear Ronald Warren,

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,

Melissa A. Torres -S

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

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)*
K142106

Device Name
Decisio Health Patient Dashboard

Indications for Use *(Describe)*
The Decisio Health Patient Dashboard is a decision support device indicated for aggregating, displaying, and managing physiologic and other patient information. This information is generated by third party medical devices and patient information systems. The device performs automated calculations on patient data collected by third party devices based on approved clinical protocols at patient care facilities.

The Decisio Health Patient Dashboard is intended for use by clinicians in healthcare facilities.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

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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"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."

510(k) SUMMARY

510(k) Notification K142106

GENERAL INFORMATION

Applicant:

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U.S.A.
Phone: 713-252-8124

Contact Person:

Ronald S. Warren
Regulatory Consultant for Decisio Health, Inc.
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755 N. Mathilda Ave, Suite 100
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U.S.A.
Phone: 1-408-505-3926
FAX: 1-408-400-0865

Date Prepared: January 8, 2015

DEVICE INFORMATION

Trade Name:

Decisio Health Patient Dashboard

Generic/Common Name:

Physiological Patient Monitor (without arrhythmia detection or alarms)

Classification:

Class II, 21 CFR§870.2300, Cardiac monitor (including cardiotachometer and rate alarm)

Product Code:

MWI, Monitor, Physiological, Patient (Without Arrhythmia Detection or Alarms)

PREDICATE DEVICES

The following predicate devices have been selected:

- AirStrip Remote Patient Monitoring RPM Remote Data Viewing software, AirStrip Technologies LP. (K100133)
- AlertWatch: OR, AlertWatch LLC (K130401)

510(k) SUMMARY

INDICATIONS FOR USE

The Decisio Health Patient Dashboard is a decision support device indicated for aggregating, displaying, and managing physiologic and other patient information. This information is generated by third party medical devices and patient information systems. The device performs automated calculations on patient data collected by third party devices based on approved clinical protocols at patient care facilities.

The Decisio Health Patient Dashboard is intended for use by clinicians in healthcare facilities.

PRODUCT DESCRIPTION

The Decisio Health Patient Dashboard ("Patient Dashboard") is a data aggregation and visualization software device. The Patient Dashboard is designed to display patient information, facility specific care protocols, and visual cues to care providers on a single display device. The Patient Dashboard is configured to receive patient data through the facility's Electronic Medical Record system and display information to the user on a patient monitor, computer, or a mobile device. Data received through the EMR includes input from various sources within the hospital, including manually entered data into the EMR (e.g., laboratory data), vital signs monitors, ventilators, IV pumps, and Foley catheter devices. The data the Patient Dashboard receives are then stored, filtered, and displayed through the Patient Dashboard web browser application. The Patient Dashboard is customized to individual facility's care as it is programmed with the facility's treatment protocols, which dictate the information that is displayed relative to those protocols. The device performs automated calculations on patient data collected by third party devices based on approved clinical protocols at patient care facilities.

SUBSTANTIAL EQUIVALENCE

The indications for use for the predicate devices are substantially equivalent to the proposed indications for use for the Patient Dashboard. Any differences in the technological characteristics between the devices do not raise new issues of safety or effectiveness. Thus, the Patient Dashboard is substantially equivalent to the predicate devices.

TESTING IN SUPPORT OF SUBSTANTIAL EQUIVALENCE DETERMINATION

All necessary testing was conducted on the Patient Dashboard to support a determination of substantial equivalence to the predicate devices. Performance testing was conducted on the Patient Dashboard to ensure that the device performs as intended per its specifications. Unit, integration, and system level testing demonstrated that the Patient Dashboard meets its specifications, including receiving data from the EMR, processing patient data according to a facility protocol, and displaying the data as expected.

Additionally, a human factors and usability study has been performed with the Patient Dashboard. The study involved 45 clinicians, who are the intended users of the Patient Dashboard. The results of the study confirmed that the Patient Dashboard design meets its intended use and the user can interpret the displayed information as intended.

510(k) SUMMARY

Therefore, performance testing verified that the device performs as intended, its design meets its intended use, and that the differences in technological characteristics between the Patient Dashboard and the predicate devices do not raise new issues of safety or effectiveness.

CONCLUSION

The Patient Dashboard has the same intended use and similar technological characteristics as do the predicate devices. The differences in technological characteristics have been analyzed and addressed through software performance testing, and human factors and usability testing. As such, the Patient Dashboard is substantially equivalent to the predicate devices.

SUMMARY

The Decisio Health Patient Dashboard is substantially equivalent to the predicate devices.