DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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August 10, 2016

Abbott Electrophysiology
Dennis Pozzo
Senior Regulatory Affairs Specialist
3668 S. Geyer Road, Suite 365
St. Louis, MO 63127

Re: K161240
Trade/Device Name: RhythmView Workstation
Regulation Number: 21 CFR 870.1425
Regulation Name: Programmable Diagnostic Computer
Regulatory Class: Class II
Product Code: DQK
Dated: July 13, 2016
Received: July 14, 2016

Dear Dennis Pozzo:

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,

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)*
K161240

Device Name
RhythmView Workstation SW V6.0.3

Indications for Use *(Describe)*
The RhythmView Workstation is a computerized system that assists in the diagnosis of complex cardiac arrhythmias. The RhythmView Workstation is used to analyze electrogram and electrocardiogram signals and display them in a visual format.

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.

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Section 5: 510(k) Summary per 21CFR §807.92

Submitter's information

Abbott Electrophysiology
3668 S. Geyer Road, Suite 365
St. Louis, MO 63127
Contact: Dennis Pozzo
Phone 314-300-6580

Device/ classification name

- Device Name: RhythmView Workstation SW V6.0.3
- Classification/Common name: Programmable diagnostic computer
- Regulation No./ Product Code: 870.1425/DQK
- The marketed device(s) to which substantial equivalence is claimed:
  - K151245, cleared Sept. 15, 2015
  - K142901, cleared Dec. 19, 2014
  - K130827, cleared Dec. 16, 2013
  - K123295, cleared April 24, 2013
  - K110878, cleared Sept. 23, 2011

Device description

The RhythmView Workstation is comprised of the following components:

Cart	Keyboard
Monitor/Display	Mouse
Computer	Two Port USB Switch
Radio-Frequency Identification (RFID) Reader/Writer	Solid State Hard Drive (optional component)
Software	

RhythmView takes electrical signals collected from multi-polar electrophysiology catheters and outputs a graphic display that assists in the diagnosis of cardiac arrhythmias.

The RhythmView computes and displays electrical rotors or focal beat sources that may sustain human heart rhythm disorders including focal AT, AFL, other SVT, AF, VT and VF in a given patient. The product takes as input electrical signals recorded during the heart rhythm disorder under consideration, typically from multiple specified locations within the heart during an electrophysiological study. The RhythmView then uses proprietary patented algorithms and methods to compute spatial organization during the heart rhythm disorder. These computed elements are displayed graphically in interactive form for review to aid diagnosis by the physician during an electrophysiology study.

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Section 5: 510(k) Summary per 21CFR §807.92, Continued

Indications for use

The RhythmView Workstation is a computerized system that assists in the diagnosis of complex cardiac arrhythmias. The RhythmView Workstation is used to analyze electrogram and electrocardiogram signals and display them in a visual format.

Technological characteristics

The RhythmView Workstation currently allows the user to:

- Review and select a time sequence of electrical signals from various electrodes;
- Analyze the signals;
- View a graphic display (Electrical Activity) of the signal potentials showing progressive depolarization and repolarization in greyscale for the particular arrhythmia;
- Play/Replay the animated graphic representation of electrical signals.
- Review various display options to assist the provider with the identification of arrhythmia patterns.
- Stream near real time electrograms from an EP recording system to RhythmView Workstation ("Streaming electrograms")
- Evaluate the quality of the electrograms exported from the EP system to RhythmView Workstation ("Signal quality indicator" (SQI))
- Use RAP improvements ("RAP intensity scale" and "Spotlight" feature)
- Create a procedure history within RhythmView ("Procedure Notebook")

The RhythmView software is being modified to improve the feedback available to the treating physician during a RhythmView procedure by incorporation of the following new features:

- A mechanism to display the composite RAP profile (Stability Map) over the entire epoch under analysis (vs. just a single 4-second time segment)
- A method of thresholding the Stability Map image analysis tool for delineating the persistence of RAP over the course of the entire epoch
- A mechanism for displaying and selecting all time segments within an epoch ("epoch timeline")
- Update of the "Procedure Notebook" to allow the user to add freeform text notes.

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Section 5: 510(k) Summary per 21CFR §807.92, Continued

Device Characteristic	Predicate RhythmView Workstation	Proposed RhythmView Workstation
Signal processing	Yes	Yes
Post-processing display	Yes	Yes
Grid display of electrode signals	Yes	Yes
Programming Language	C++	C++
Export of processed file into video format	Yes	Yes
OTS Software requirements	Same	Same
Display options for review of processed signals	• Electrical Activity • Depol Contours • Repol Contours • Rotational Activity Profile	• Electrical Activity • Depol Contours • Repol Contours • Rotational Activity Profile
RAP display (optional)	Multi-color with monochromatic option available	Multi-color with monochromatic option available
RFID Reader/Writer Function	Yes	Yes
Data transfer via Two Port Switch	Yes	Yes
Direct data transfer via USB cable to RV Workstation from EP system	Option available	Option available
Atrial Function	Yes	Yes
Ventricular Function	Option available	No
Signal Quality Indicator	Yes	Yes
Spotlight Feature	Yes	Yes
Streaming real time electrograms	Option available	No
Notebook Procedure	Yes	Yes
Stability Map	No	Option available
Epoch Timeline	No	Option available

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Section 5: Summary per 21CFR §807.92, Continued

Device Characteristic (Technological Comparison)	Predicate RhythmView Workstation	Proposed RhythmView Workstation
Electrical Rating		
Electrical rating – Typical	120V, 60Hz	120V, 60Hz
Battery	40 Ah, 12 V DC, Lithium Iron Phosphate	40 Ah, 12 V DC, Lithium Iron Phosphate
RF Class per CISPR11	Group1	Group 1

Applicable standards

- ISO 14971: 2012, Medical Devices - Application of risk management to medical devices

Since there are no hardware updates, the EMC and Electrical Safety reports provided in K151245 still apply.

- IEC 60601-1, 3rd Edition, Medical electrical equipment – Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-2: 2007, Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility – Requirements and tests

Performance data

Bench testing has been conducted through software and user verification/ validation protocols to ensure the RhythmView Workstation meets its intended use and user needs.

The testing encompassed:

- Validation of the Stability Map and the default Stability Filter setting using clinical data sets
- Verification that the Stability Maps generated by RhythmView are correct compilations of the RAP profiles from individual segments
- Physician validation to confirm that the activation maps with and without RAP lead to a consistent diagnosis
- Simulated User testing to evaluate new features of UI

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Section 5: 510(k) Summary per 21CFR §807.92, Continued

Performance data, continued

Conclusion

The testing has demonstrated that the SW updates for RhythmView V6.0 provide reasonable assurance that the proposed device conforms to the appropriate requirements for its intended use. Therefore, it is substantially equivalent to the predicate device, safe and effective for its intended use.