September 1, 2017

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

Re: K171583
Trade/Device Name: RhythmView Workstation 6.1
Regulation Number: 21 CFR 870.1425
Regulation Name: Programmable Diagnostic Computer
Regulatory Class: Class II
Product Code: DQK
Dated: August 4, 2017
Received: August 8, 2017

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 (DICE) 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 (DICE) 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,

[Signature]

for

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

Enclosure
Indications for Use

510(k) Number (if known)
K171393

Device Name
RhythmView Workstation 6.1

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.

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

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FORM FDA 3881 (7/17)
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 6.1
- Classification/Common name: Programmable diagnostic computer
- Product Code/Classification No.: DQK/21 CFR 870.1425
- The marketed device to which substantial equivalence is claimed:
  RhythmView Workstation, K161240, cleared August 10, 2016
  RhythmView Workstation, K151245, cleared September 15, 2015
  (ventricular function)

Device description
RhythmView uses electrical signals collected from the electrodes of one or more multi-polar electrophysiology (EP) catheters. It provides a dynamic, simplified representation of wave propagation.

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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**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.
- Evaluate the quality of the electrograms exported from the EP system to RhythmView Workstation ("Signal quality indicator" (SQI))
- Enable an option to improvements usability of RAP ("RAP intensity scale" and “Spotlight” feature)
- Review 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")
- Create a procedure history within RhythmView ("Procedure Notebook") and allow the user to add freeform text notes.

The RhythmView software is being modified to improve the feedback and usability during a RhythmView procedure by updating the following functions:

- Caliper tool;
- ECG lead;
- SQI;
- RAP calculation; and
- Stability map

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

<table>
<thead>
<tr>
<th>Device Characteristic</th>
<th>Predicate RhythmView Workstation</th>
<th>Proposed RhythmView Workstation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Signal processing</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Post-processing display</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Grid display of electrode signals</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Programming Language</td>
<td>C++</td>
<td>C++</td>
</tr>
<tr>
<td>Export of processed file into video format</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>OTS Software requirements</td>
<td>Same</td>
<td>Same</td>
</tr>
</tbody>
</table>

#### Device Characteristic: Display options for review of processed signals

- **Electrical Activity**
- **Contours Only**
- **DContours**
- **Rotational Activity Profile**
- **Composite RAP image (“Stability Map”)**
- **Epoch timeline**
- **Spotlight**

- **Electrical Activity**
- **Contours Only**
- **DContours**
- **Rotational Activity Profile**
- **Composite RAP image (“Stability Map”)**
- **Epoch timeline**
- **Spotlight**

- **Multi-color with monochromatic option available**

#### Device Characteristic: RAP display (optional)

- **Multi-color with monochromatic option available**

#### Device Characteristic: RFID Reader/Writer Function

- Yes

#### Device Characteristic: Data transfer via Two Port Switch

- Yes

#### Device Characteristic: Direct data transfer via USB cable to RV Workstation from EP system

- Option available

#### Device Characteristic: Atrial Function

- Yes

#### Device Characteristic: *Ventricular Function

- Option not available

#### Device Characteristic: Signal Quality Indicator

- Option available

#### Device Characteristic: Procedure Notebook

- Option available

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Section 5: Summary per 21CFR §807.92, Continued

<table>
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<tr>
<th>Device Characteristic</th>
<th>Predicate RhythmView Workstation</th>
<th>Proposed RhythmView Workstation</th>
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</thead>
<tbody>
<tr>
<td><strong>Spotlight Feature</strong></td>
<td>Option available</td>
<td>Option available</td>
</tr>
<tr>
<td><strong>Stability Map</strong></td>
<td>Option available</td>
<td>Option available</td>
</tr>
<tr>
<td><strong>Epoch Timeline</strong></td>
<td>Option available</td>
<td>Option available</td>
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</tbody>
</table>

**Electrical Rating (Technological Comparison)**

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<table>
<thead>
<tr>
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<tbody>
<tr>
<td>Electrical rating –</td>
<td>120V, 60Hz</td>
<td>120V, 60Hz</td>
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<tr>
<td>Typical</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Battery</td>
<td>40 Ah, 12 V DC, Lithium Iron</td>
<td>40 Ah, 12 V DC, Lithium Iron</td>
</tr>
<tr>
<td></td>
<td>Phosphate</td>
<td>Phosphate</td>
</tr>
<tr>
<td>RF Class per CISPR11</td>
<td>Group 1</td>
<td>Group 1</td>
</tr>
</tbody>
</table>

*Ventricular Function: predicate 510(k) K151245  
**Atrial function only

**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 referenced K161240 still apply.

- IEC 60601-1, 3rd Edition, Medical electrical equipment – Part 1: General requirements for basic safety and essential performance

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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 Summation Maps generated are correct compilations of the RAP profiles from individual segments
- Validate that RAP detects known rotational targets at least as well as prior versions of RAP.
- Validate the RAP functionality in RhythmView through Physician reads
- Simulated User testing to evaluate new features of UI

Conclusion

The testing has demonstrated that the SW updates for RhythmView V6.1 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.