



Food and Drug Administration
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December 19, 2014

Topera, Inc.
Dennis Pozzo
Senior Regulatory Affairs Master Specialist
3668 S. Geyer Road, Suite 365
St. Louis, Missouri 63127

Re: K142901
Trade/Device Name: Rhythmview Workstation
Regulation Number: 21 CFR 870.1425
Regulation Name: Programmable Diagnostic Computer
Regulatory Class: Class II
Product Code: DQK
Dated: November 24, 2014
Received: November 25, 2014

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,

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

Enclosure

Indications for Use

510(k) Number (if known)

K142901

Device Name

RhythmView Workstation

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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Appendix 1: 510(k) Summary per 21CFR §807.92**Submitter's information**

Topera, Inc.
3668 S. Geyer Road, Suite 365
St. Louis, MO 63127
Contact: Dennis Pozzo
Phone 314-300-6580
Date: May XX, 2014

Device/ classification name

- Device Name: RhythmView™ Workstation
- Classification/Common name: Programmable diagnostic computer
- The marketed device(s) to which substantial equivalence is claimed:
 - 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	Software
Radio-Frequency Identification (RFID) Reader/Writer (new component)	Two Port USB Switch (new component)
Solid State Hard Drive (new optional component)	

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 responsible for maintaining 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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Appendix 1: 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 Both the proposed and predicate RhythmView™ Workstations are software driven devices that translate electrical signals within the heart into graphic representations in order to assist the physician in diagnosis. They also allow 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 grayscale for the particular arrhythmia;
- Play/Replay the animated graphic representation of electrical signals.

Furthermore,

- The ventricular maps appear in the panoramic animation display in the same manner as atrial maps.
 - All of the same display options available in atrial maps may be used for ventricular maps.
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Appendix 1: 510(k) Summary per 21CFR §807.92, Continued

Device Characteristic	Predicate Device RhythmView™ 4.1	Proposed Device RhythmView™ 4.2
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
Manual tagging by user of electrograms	No	No
OTS Software requirements	Same	Same
Display options for review of processed signals	<ul style="list-style-type: none"> • Electrical Activity • Contours Only • DContours • Rotational Activity Profile 	<ul style="list-style-type: none"> • Electrical Activity • Contours Only • DContours • Rotational Activity Profile”
RFID Reader/Writer Function	No	Yes
Data transfer via Two Port Switch	No	Yes
Direct data transfer via USB cable to RV Workstation from EP system	No	Option available
Atrial Function	Yes	Yes
Ventricular Function	No	Option available

Performance data

The Software, Hardware (RFID, Two Port USB Switch and SSD Qualification Testing and EMC Testing) and User testing that have been performed provide reasonable assurance that the proposed device has been tested to verify conformance to requirements for its intended use. Therefore, it has been demonstrated that the RhythmView™ Workstation is safe and effective for its intended use.