



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

Topera, Inc.
Dennis Pozzo
Sr. Regulatory Affairs Specialist
3668 S. Geyer Road
Suite 365
St. Louis, MO 63127

Re: K151245
Trade/Device Name: RhythmView Workstation SW V5.0
Regulation Number: 21 CFR 870.1425
Regulation Name: Programmable Diagnostic Computer
Regulatory Class: Class II
Product Code: DQK
Dated: May 8, 2015
Received: May 11, 2015

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.

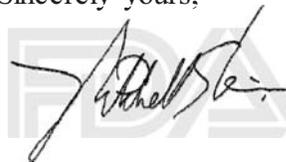
If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<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,

A handwritten signature in black ink, appearing to read "Bram D. Zuckerman", is written over a large, faint, light-colored watermark of the FDA logo.

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)

K151245

Device Name

RhythmView Workstation SW V5.0

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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"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."

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

Device/ classification name

- Device Name: RhythmView Workstation, SW V5.0
- Product Code: DQK
- Classification No: 21 CFR 870 1425
- Classification/Common name: Programmable diagnostic computer
- The marketed device(s) to which substantial equivalence is claimed:
 - 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	Video Splitter (new component - streaming option only) <i>*Panel box required</i>
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 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.
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Technological characteristics	<p>Both the proposed and predicate RhythmView Workstations allows the user to:</p> <ul style="list-style-type: none"> • 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. • All display options are available for both atrial and ventricular maps. <p>Other than the additional display options (SQI, Multi-color RAP and the spotlight feature) associated with the proposed RhythmView workstation, the major difference between the predicate and proposed workstation is the addition of the optional streaming and associated SQI of the streaming data.</p> <p>It is important to note that the import of the streaming electrograms vs. non-streaming electrograms is identical with the exception of a few new workflow steps.</p>
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Performance data	The Software and Hardware (video splitter, panel box and computer) had undergone verification and validation testing, including Electrical Safety and EMC testing to provide reasonable assurance that the proposed device conforms to the appropriate requirements for its intended use. The Workstation has also undergone usability testing. Therefore, it has been demonstrated that the RhythmView Workstation is safe and effective for its intended use.
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Consensus standards	IEC 60601-1-2 Medical Electrical Equipment, General requirements for safety. Electromagnetic Compatibility and essential performance IEC 62366 Medical Devices - Application of Usability Engineering to Medical Devices
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Appendix 1: 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
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”
RAP display (optional)	Monochromatic only	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	Option available
Signal Quality Indicator	No	Yes
Spotlight Feature	No	Yes
Streaming real time electrograms	No	Option available