December 1, 2022

Rhythm AI Ltd.
℅ Linda D'Abate
VP, Regulatory, Clinical & Quality
124 Gilbert Stuart Drive
East Greenwich, Rhode Island 02818

Re: K220786
Trade/Device Name: STAR Apollo™ Mapping System
Regulation Number: 21 CFR 870.1425
Regulation Name: Programmable Diagnostic Computer
Regulatory Class: Class II
Product Code: DQK
Dated: October 27, 2022
Received: October 28, 2022

Dear Linda D'Abate:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Aneesh S. Deoras -S

Aneesh Deoras
Assistant Director
Division of Cardiac Electrophysiology,
Diagnostics and Monitoring Devices
Office of Cardiovascular Devices
Office of Product Evaluation and Quality
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K220786

Device Name
STAR Apollo™ Mapping System

Indications for Use *(Describe)*
STAR Apollo™ Mapping System assists users in manual annotation of 3D anatomical and electrical maps of human atria using data from multipolar, intracardiac, atrial, electrograms during atrial fibrillation. The clinical significance of utilizing the STAR Apollo Mapping System, to help identify areas with intracardiac atrial electrograms, of atrial arrhythmias, such as atrial fibrillation, has not been established by clinical investigations.

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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510(k)Summary

1) **SUBMITTER**

Rhythm AI Ltd.
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Witney, Oxfordshire
OX29 7DX
United Kingdom
Phone: (714) 235-6608
website: n/a

Contact Person: Linda D'Abate
Date Prepared: October 27, 2022

2) **DEVICE**

510(k) Number: K220786
Name of Device: STAR Apollo™ Mapping System
Common or Usual Name: Electroanatomic mapping system
Classification Name: Programmable, Diagnostic, Computer
Regulation Number: 21 CFR 870.1425
Regulatory Class: II
Product Code: DQK

3) **PREDICATE DEVICE**

510(k) Number: K201298
Primary Predicate: VX1 manufactured by Volta Medical

4) **DEVICE DESCRIPTION**

The STAR Apollo™ Mapping System is a software driven system designed to assist operators in identifying Early Site of Activations (ESA) and Repetitive Patterns of Activation (RPA) in patients undergoing a cardiac mapping procedure for Atrial Fibrillation (AF). The software is designed for use in association with a commercially approved electroanatomic mapping system, specifically, Ensite Precision Cardiac Mapping System Model EE 3000 (V2.6) or Ensite X EP System (V 1.1.1) (Abbott Medical), and the commercially approved catheter, Advisor™ HD Grid Mapping Catheter, Sensor Enabled™ (Abbott Medical).

The STAR Apollo Mapping System is a cardiac mapping method that is based on proprietary algorithms developed to identify localized sources of atrial activation during AF . The STAR Apollo Mapping System does not aim to elucidate the mechanism of AF, rather it seeks to reveal the anatomical location of regions where activation may be originating from, regardless of mechanism. This is based on a very simple and fundamental principle that the source of activation will have activation emerging from it in multiple directions, but not progressing towards it.

The system consists of proprietary Star Apollo Mapping System software and a hardware component. Star Apollo Mapping System software consists of 3 main components:

Electroanatomic data import, the STAR Apollo Mapping System engine (C++ code) and Graphics User Interface (GUI). The STAR Apollo Mapping System is designed to run on a laptop computer running Windows 10 or later operating system. Star Apollo Mapping System software is pre-installed onto the laptop.

The STAR Apollo Mapping System uses export data from the Ensite Precision or Ensite X EP system that has been collected with the HD Grid catheter during the mapping procedure. The HD Grid is used to collect anatomy, localization and electrogram data in the atria. Recordings are made for 30 seconds with the HD Grid in a stable position and in contact with the atrial wall. These 30 seconds acquisitions are made in multiple, non-overlapping locations, so as to generate recordings over the entire atrial chamber. Once the data has been acquired, the data is anonymized and exported, via a portable external data storage device, to the laptop computer running the STAR Apollo Mapping System. The export data from the Ensite Precision or Ensite X EP systems consists of electrograms, electrode coordinates, ECG recordings and the geometry model. The data are imported, utilizing the portable external data storage device, into the STAR Apollo Mapping System and then processed by the STAR Apollo engine to generate a STAR Apollo map visualized by the GUI.

The STAR Apollo Mapping System operates outside the sterile field and is not connected directly to the Ensite Precision or Ensite X EP mapping system, or any other devices used in the procedure. The system uses the data transferred, via a portable external data storage device, from the Ensite Precision or Ensite X EP mapping system, which is then disconnected from that Ensite Precision or Ensite X EP mapping system and then loaded onto the laptop computer running STAR Apollo Mapping System software. No data is transferred from the STAR Apollo Mapping System back to the Ensite Precision or Ensite X EP mapping system i.e. data transfer is only in one direction. No modifications to the Ensite Precision or Ensite X EP mapping systems are made to accommodate the STAR Apollo Mapping System. The Star Apollo maps may be used to give physicians information about the AF activations. The physicians may use them as an additional aid to identify areas within the atria that may warrant further and close examination using the Ensite Precision or Ensite X EP mapping system, and the HD Grid catheter. The system is never directly connected to a patient, nor does it deliver therapy. It is used as a software tool that provides supplementary information to the physician. The STAR Apollo Mapping System is intended to be used in an electrophysiology procedure and/or outside of the electrophysiology lab.

5) **STATEMENT OF INDICATION for USE**

STAR Apollo™ Mapping System assists users in manual annotation of 3D anatomical and electrical maps of human atria using data from multipolar, intracardiac, atrial, electrograms during atrial fibrillation. The clinical significance of utilizing the STAR Apollo Mapping System, to help identify areas with intracardiac atrial electrograms, of atrial arrhythmias, such as atrial fibrillation, has not been established by clinical investigations.

6) SUMMARY OF NON-CLINICAL TESTING

The following testing was conducted to demonstrate substantial equivalence to the primary predicate.

- **Software design verification testing**
  - *Algorithm description and testing*- Identification of each of the algorithms within the software code and testing to demonstrate that the mathematical calculations performed by the software match that of the correct, predetermined output.
  - *Verification of algorithm calculations and graphic output* – Test cases were performed for each of the software requirement specifications and demonstrated that the software performance met the acceptance criteria for each of the test cases and both numerical and graphical output was correct.
- **Software design validation testing**
  - *Blinded Physician Validation* (Manual Annotation versus STAR Apollo Mapping System) – Simulated testing was completed with electrophysiologists performing manual annotation of ECGs and comparing the results with the STAR Apollo Mapping System. Testing demonstrated that manual annotation yielded similar results to the STAR Apollo Mapping System output.
  - *STAR Apollo Physician Use*- Simulated testing was completed with electrophysiologists and rated the overall use of the STAR Apollo Mapping System software. Testing demonstrated that the STAR Apollo System Mapping System software was appropriate for use.

7) TECHNOLOGICAL CHARACTERISTICS AND COMPARISON TO PREDICATE

The STAR Apollo Mapping System and its predicate Volta VX1(K201298) both work with standard electrophysiology catheters to aid in mapping the atria. The predicate device outputs multiple real-time sequential annotation in order to complete a global assessment of the atria (the map updates each time an acquisition is processed but the aim is to map the entire atria to produce a global assessment after multiple analysis). The STAR Apollo device outputs information as a single global output of sequentially acquired input data (the map produced is global and is a single analysis of multiple sequential acquisitions). Both are separate stand alone software systems. Whether these functions are presented sequentially, or as one global map of sequentially acquired data in real-time, or performed separately during the same procedure, does not affect the subject device's performance nor raise different questions of safety or effectiveness. The information provided is used independently from the clinical procedure, and requires further clinical validation by the physician before any mapping or treatment decisions are made.

In particular, the STAR Apollo Mapping System performs an equivalent function to the Volta VX1 device. Both devices aid operators by assisting in annotating complex electrical maps of the atria, and both devices process and output information, via a computer and displays that are operated by use of a keyboard/mouse. Additionally, the input data used by STAR Apollo Mapping System software are of the same nature (multipolar atrial electrograms) as those used by the Volta VX1 device. Both devices also have similar outputs, the results of analysis of these signals and representation of this analysis on a computer display.

The STAR Apollo Mapping System software performs analysis of individual per procedural data sets, with the algorithms based on fundamental principles of electrophysiology, in order to replicate what a physician would do manually, given sufficient time. VX1 also automates the process that can be performed manually, but the analytical parameters pertain to recordings of previous procedures. VX1 is a software that utilizes deep learning based algorithms to analyze data sets, whereas the STAR Apollo Mapping System software uses fixed algorithms and equations to analyze the data sets. Both STAR Apollo Mapping system software and VX1 are not connected to

a server network.

Like the predicate device, the STAR Apollo Mapping System assists in the annotation of complex 3D anatomical and electrical maps of the human atria, including the presence of multipolar electrograms. Thus, both the subject and predicate device have similar intended use.

Neither device is intended for directing treatment or affecting the outcome of any particular heart arrhythmia.

	SUBJECT DEVICE	PRIMARY PREDICATE	COMPARISON
	STAR Apollo Mapping System	Volta VX1	Subject Device to Predicates
<u>Regulatory</u>			
510(k) Number	K220786	K201298	
Regulation No. (s)	21 CFR 870.1425	21 CFR 870.1425	Identical
Product Code (s)	DQK	DQK	Identical
Indications for Use	STAR Apollo™ Mapping System assists users in manual annotation of 3D anatomical and electrical maps of human atria using data from multipolar, intracardiac, atrial, electrograms during atrial fibrillation. The clinical significance of utilizing the STAR Apollo mapping system, to help identify areas with intracardiac atrial electrograms, of atrial arrhythmias, such as atrial fibrillation, has not been established by clinical investigations.	The VX1 assists operators in real-time manual annotation of 3D anatomical and electrical maps of human atria for the presence of multipolar intracardiac, atrial, electrograms exhibiting spatiotemporal dispersion during atrial fibrillation or atrial tachycardia. The clinical significance of utilizing the VX1 software to help identify areas with intracardiac atrial electrograms exhibiting spatiotemporal dispersion for catheter ablation of atrial arrhythmias, such as atrial fibrillation, has not been established by clinical investigations.	Similar. Like the predicate, both STAR Apollo Mapping System and VX1 assist operators in manual annotation of anatomical and electrical maps of human atria, using data from multipolar, intracardiac electrograms during atrial fibrillation. STAR Apollo Mapping identifies areas with intracardiac electrograms showing repetitive patterns of activation (RPA) including earliest site of activation (ESA); while VX1 identifies areas with intra-cardiac atrial electrograms exhibiting spatiotemporal dispersion. The STAR mapping system uses algorithms to analyze and summarize AF repetitive activation patterns, allowing physicians to understand how the AF may be activating the atrium. The VX1

	SUBJECT DEVICE	PRIMARY PREDICATE	COMPARISON
	STAR Apollo Mapping System	Volta VX1	Subject Device to Predicates
			uses an algorithm to analyze electrograms and identify dispersed regions. Both the STAR Apollo Mapping system and the VX1 simply provides complimentary additional information regarding atrial fibrillation to the user in addition to the information provided by mapping systems. The clinical significance of both the STAR Apollo Mapping system and VX1 have not been established by clinical investigation. Neither device is intended for directing treatment or affecting the outcome of any particular atrial arrhythmia. The slight difference between the subject device and the predicate device does not alter the intended diagnostic effect and does not introduce any new issues of safety or efficacy
Intended Use Population	Individuals undergoing EP procedures	Individuals undergoing EP procedures	Identical
Intended Use Environment	Clinical and hospital environment	Clinical and hospital environment	Identical

510(k)Summary

	SUBJECT DEVICE	PRIMARY PREDICATE	COMPARISON
	STAR Apollo Mapping System	Volta VX1	Subject Device to Predicates
Prescription (Rx Only)/ Over-the-Counter	Prescription Only	Prescription Only	Identical
Device Design	Electrophysiological mapping of the atria with visual cues for analysis of atrial fibrillation using software	Electrophysiological mapping of the atria with visual cues for analysis of atrial fibrillation using software	Identical
Mapping Display Principal Mapping Approach	The physician transfers the export data into the STAR Apollo Mapping System software. The STAR Apollo Mapping System performs calculations and computations using the input data. The STAR Apollo Mapping System displays a graphical representation of the anatomy of the heart atrial chamber overlaid with the Early Activation Sites (ESAs) and Repetitive Patterns of Activation(RPAs) for atrial fibrillation.	Displays adjudications as visual cues after analyzing intracardiac atrial electrograms in real-time using signal processing and deep and machine learning techniques	Similar, both subject device and predicate device provide graphics based upon input data. STAR Mapping system displays ESAs and RPAs overlaid a graphical representation of the anatomy; VX1 displays the electrode locations on a catheter model without the anatomy of the heart atrial chamber.
Cardiac Model Used	Using the individualized, patient-specific anatomical model created with the 3D mapping systems. The locations are displayed relative to the mapping catheter electrodes overlaid with the anatomical model.	The locations are displayed relative to the mapping catheter electrodes.	Similar, the locations of interest of both the subject device and the predicate device and both are displayed as the output graphical data. The anatomical representations may assist the physicians in interpreting the electro-physiological data as demonstrated by the verification and validation studies.
Cardiac Maps Provided	The STAR Apollo Mapping System displays graphical representation of the anatomy of a heart chamber overlaid with Early Activation Sites (ESAs) and Repetitive Activation Patterns (RPAs) using stable contact multipolar catheter recording during atrial fibrillation to	The map type generated by VX1, is a real-timed Dispersed Electrograms (DE) subtype of multipolar electrogram map. The operator is provided with a display of the electrode locations where dispersed or non-dispersed electrograms have been recorded during atrial fibrillation or atrial	Similar. Both the STAR Apollo Mapping system and the VX1 simply provides complimentary additional information regarding atrial fibrillation to the user, in addition to the information provided by mapping systems.

	SUBJECT DEVICE	PRIMARY PREDICATE	COMPARISON
	STAR Apollo Mapping System	Volta VX1	Subject Device to Predicates
	provide insights of atrial fibrillation.	tachycardia.	
System Type	Signal processing-based atrial mapping system	Signal processing-based atrial mapping system	Identical
Display(s)	Color Monitor	Color Monitor	Identical
Control	Laptop keyboard/mouse/trackpad/touchscreen.	Standard keyboard/mouse	Laptop keyboard versus standard keyboard. STAR Apollo additionally has trackpad and touchscreen for additional usability by physicians, as demonstrated by verification and validation studies.
<u>Principles of Operation</u>			
Software Driven Analysis	Yes	Yes	Identical
Reports of Diagnostic Results	No	No	Identical
Electrophysiological Cardiac Input	Yes, Patient-specific intracardiac electrogram information (acquired by compatible catheter)	Yes. Patient -specific intracardiac electrogram information (acquired by compatible catheter	Identical
Principal Mapping Output	Displays visual cues after analyzing intracardiac atrial electrograms using signal processing techniques (not in real-time)	Displays adjunctions as visual cues after analyzing intra-cardiac atrial electrograms in real-time using signal processing techniques	Identical with the exception of real time for Volta VX1. The lack of not being performed in real time does not affect the performance of STAR Apollo's functionality.
Compatible Catheters	Advisor HD Grid Mapping Catheter, Sensor Enabled	Any compatible catheter meeting the requirements	Although Volta specifies a broader range of specified

	SUBJECT DEVICE	PRIMARY PREDICATE	COMPARISON
	STAR Apollo Mapping System	Volta VX1	Subject Device to Predicates
	(K172393)	listed below: Compatibility Requirements: Mapping catheter: -Electrodes size: 1mm -Inter-electrode spacing: 2-3 mm -Number of dipoles: 10 Coronary sinus catheter -Electrode size: 1mm -Inter electrode Spacing: 2-3 mm -Number of selected dipoles: 5 Note: The Advisor HD Grid Mapping Catheter, Sensor Enabled, recommended by Rhythm AI, is within the range of the above stated compatibility parameters for the catheters	catheters when compared to the Rhythm AI recommended single catheter, it does not change the performance relative to atrial mapping and does not raise different questions of safety or effectiveness.
Compatible System	Ensite Precision Cardiac Mapping System Model EE 3000 (V2.6) (K201148) Ensite X EP System (V 1.1.1) (K213364)	2D Acquisition Data System: LabSystem Pro, Acquisition System (Boston Scientific) (K141185) and MacLab CardioLab Acquisition System (General Electric) (K130626).	Similar STAR Apollo Mapping system uses a 3D electro-anatomical mapping system versus a 2D mapping system which does not change the safety and efficacy of the subject device and the predicate.
Hardware Design and Materials Used	Off-the Shelf information technology (IT) hardware: Laptop computer and screen, connection cable, acquisition USB, proprietary software algorithm	Off-the-shelf information technology (IT) hardware: computer and monitor, connection cable, acquisition system, proprietary software algorithm	Similar STAR Apollo Mapping System uses a laptop computer and utilizes a USB to transfer the acquisition data to the STAR Apollo Mapping System. Both the subject device and the predicate device use proprietary software algorithms.

8) CONCLUSION

The STAR Apollo Mapping System software and it predicate both work with standard electrophysiology catheters to aid in mapping the human atria. Both STAR Apollo Mapping System and VX1 assist operators in manual annotation of anatomical and electrical maps of human atria, using data from multipolar, intracardiac electrograms during atrial fibrillation.

Specifically, the STAR Apollo Mapping System software is substantially equivalent to the VX1 device. In particular, the STAR Apollo Mapping System performs an equivalent function to the VX1 device and works with mapping systems and compatible catheters to form a system which is equivalent to the predicate system. The STAR Apollo Mapping System and VX1 have similar technological characteristics and principles of operation. The signals identified by the STAR Apollo Mapping System software are of the same nature (multipolar electrograms) and have the same input (intra-cardiac atrial signals) and have similar output. The STAR Apollo Mapping System software has the same intended use and similar indications, technological characteristics, and principles of operation as its predicate device. The minor differences in indications do not alter the intended use of the device as an electrophysiological evaluation tool. In addition, the minor technological differences of the STAR Apollo Mapping System software does not affect substantial equivalence to the predicate. Performance data, as described above, demonstrate that the STAR Apollo Mapping System software is as safe and effective as the predicate. Thus, the STAR Apollo Mapping System software is substantially equivalent.