December 19, 2025

Rhythm AI, Ltd.
Linda D'Abate
VP, Regulatory, Clinical and Quality
One London Wall, 6th Floor
London, EC2Y 5EB
United Kingdom

Re: K253733
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: November 24, 2025
Received: November 24, 2025

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

for MARCO CANNELLA -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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K253733

Device Name

STAR Apollo™ Mapping System

Indications for Use *(Describe)*

STAR Apollo™ Mapping System assists users in the interpretation and 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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London, EC2Y 5EB
United Kingdom
website: www.rhythm-ai.com
Contact Person: Linda D'Abate
Phone: (714) 235-6608
Date Prepared: Nov. 24, 2025

2) **DEVICE**

510(k) Number: K253733
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: K240509
Primary Predicate: STAR Apollo™ Mapping System manufactured by Rhythm AI, Inc.

4) **DEVICE DESCRIPTION**

The STAR Apollo Mapping System (v1.8) is a software driven system designed to assist operators in identifying Early Sites of Activation (ESA) and Repetitive Patterns of Activation (RPA) in patients undergoing a cardiac mapping procedure for Atrial Fibrillation (AF). The software is designed for use with FDA cleared electroanatomic mapping systems specifically:

- CARTO™ 3 EP Navigation System (V8.1) (K252302) (Biosense Webster) and
    - OPTRELL™ Mapping Catheter with TRUEref™ Technology (K230253) (Biosense Webster)

for exporting geometry data, electrograms and electrode locations over ethernet connection during the electrophysiology procedure with CARTO 3 API (K231207) to provide input data for the STAR Apollo Mapping System.

- Ensite Precision Model EE 3000 Cardiac Mapping System (V2.6) (K201148) and
    - Advisor™ HD Grid Mapping Catheter, Sensor Enabled™ (K172393) (Abbott Medical) or
- EnSite X EP System (V 1.1.1, V 2.0, V 3.0) (K213364) (K221213) (K231415) (Abbott Medical) and
    - Advisor™ HD Grid Mapping Catheter, Sensor Enabled™ (K172393) (Abbott Medical) or
- Ensite X EP System (V 3.1) (K242016) (Abbott Medical) and either:
    - Advisor™ HD Grid Mapping Catheter, Sensor Enabled™ (K172393) (Abbott Medical) or
    - Advisor™ HD Grid X Mapping Catheter, Sensor Enabled™ (K242016) (Abbott Medical)

for exporting geometry data, electrograms and electrode locations via a portable external storage device or over ethernet data connection (Ensite X EP System (V 3.0, V 3.1) with LiveSync module) (K231415)

(K242016) during the electrophysiology procedure to provide input data for the STAR Apollo Mapping System.

The principle of STAR Apollo Mapping System analysis is to use data on multiple individual wavefront trajectories to identify Repetitive Patterns of Activation (RPA) or regions of the atrium that represent Early Sites of Activation (ESA) which most often precede activation of neighboring areas, with the aim of helping clinicians to identify regions of the atria that may be the origins for AF activation. 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 11 Operating System. STAR Apollo Mapping System software is pre-installed onto the laptop.

The STAR Apollo Mapping System uses export data from the compatible Mapping System that has been collected with the compatible Mapping Catheter during the electrophysiology procedure. The Mapping Catheter is used to collect anatomy and electrogram data in the atria. Recordings are made for at least 30 seconds with the Mapping Catheter in a stable position and in contact with the atrial wall. These ≥30 second acquisitions are made in multiple, non-overlapping locations, to generate recordings over the entire atrial chamber. The data is exported via an external portable storage device or by streaming via an ethernet data cable connected to the data ethernet port of the EnSite X or CARTO 3 workstation. It is transferred to the laptop computer running the STAR Apollo Mapping System. The export data accepted from the Mapping Systems consists of electrograms, electrode coordinates, ECG recordings and the geometry model. The data is imported utilizing the portable external data storage device or via ethernet 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 Map will highlight sites deemed to be Early Sites of Activation (ESA), as a red sphere at the endocardial locations corresponding to the recording electrode position. These sites are areas where the myocardium has initiated activation earlier than its neighboring sites on multiple occasions and therefore may be a potential site of AF initiation or maintenance. The more repetitive these sites are, the larger the red sphere appears on the STAR Apollo Map. The system will rank the ESA according to their repetition frequency and cycle length and identify the most relevant 3 sites. The system is designed to show the physician Repetitive Patterns of Activation (RPA). These are shown as colored arrows, which start from the leading electrode position, following the summarized activation sequence. The more repetitive or consistent that activation pattern is, the wider the white arrow. Based on this information the physicians may then use this as an additional guide for further mapping of the AF, using FDA cleared mapping system catheters.

The STAR Apollo Mapping System operates outside the sterile field and is only connected to the EnSite Precision, EnSite X EP or CARTO 3 workstation and not to the amplifier, patient, or any other devices used in the procedure. No data is transferred from the STAR Apollo Mapping System back to the EnSite Precision, EnSite X EP mapping system, or CARTO 3 i.e., data transfer is only in one direction. No modifications to the EnSite Precision, EnSite X EP mapping systems or CARTO 3 are made to accommodate the STAR Apollo Mapping System. The STAR Apollo Maps may be used to give physicians additional information about the AF activations. The physician may use them as an additional aid to identify areas within the atria that may warrant further and close examination using the mapping system, and the compatible Mapping Catheter. The STAR Apollo 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 in an electrophysiology procedure.

Description of Changes:
The STAR Apollo Mapping System (v1.8) has the following new features and software design requirements when compared to the STAR Apollo Mapping System (v1.6):

Mapping Catheter compatibility–
STAR Apollo Mapping System (v1.8) is compatible with:

- OPTRELL™ Mapping Catheter with TRUEref™ Technology

Mapping System compatibility –
STAR Apollo Mapping System (v1.8) is compatible with:

- CARTO™ 3 EP Navigation System V8.1 and CARTO 3 EP API which is compatible with the OPTRELL™ Mapping Catheter with TRUEref™ Technology.

5) **STATEMENT OF INDICATIONS for USE**

STAR Apollo™ Mapping System assists users in the interpretation and 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 STAR Apollo Mapping System (v1.8) was developed and tested in accordance with the following industry guidance documents and standards:

- Content of Premarket Submissions for Device Software Functions
- IEC 62304:2015-06 Edition 1.1, Medical Device Software - Software Life Cycle Processes
- ISO 14971:2019 Medical Devices- Application of Risk Management to Medical Devices

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

Software design verification testing

i) *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.

ii) *Verification of software/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

iii) *Physician Use*- Design validation was completed to compare the STAR Apollo Mapping System v1.8 from the two different compatible mapping systems and catheters to demonstrate equivalence in the functional performance and STAR Apollo Maps with regards to clinical workflow. Testing completed with physicians demonstrated that the STAR Apollo Maps produced were equivalent to the information shown.

7) TECHNOLOGICAL CHARACTERISTICS AND COMPARISON TO PREDICATE

The STAR Apollo Mapping System (v1.8) and its predicate STAR Apollo Mapping System (v1.6) both work with standard electrophysiology catheters to aid in mapping the atria. Both versions of the STAR Apollo Mapping System software output information operate as a single global output, with sequentially acquired input data (the map produced is global and is a single analysis of multiple sequential acquisitions). Both the predicate and the subject versions are separate standalone software systems. There are no differences between the subject and predicate device's performance that raise different or additional questions of safety or efficacy. The information provided is used independently from the clinical procedure, and requires further clinical assessment, by the physician, before any treatment decisions are made.

In particular, the STAR Apollo Mapping System (v1.8) performs an equivalent function to the STAR Apollo Mapping System (v1.6) device. Both devices aid operators by assisting in the interpretation of 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 touchscreen/mouse. Additionally, the input data used by STAR Apollo Mapping System (v1.8) software are of the same nature (multipolar atrial electrograms recordings) as those used by the STAR Apollo Mapping System (v1.6) device. Both devices also have identical outputs, the results of analysis of these signals and representation of this analysis are on a computer display.

Both versions of the STAR Apollo Mapping System software perform analysis of individual, per procedural data sets, with the algorithms, based on fundamental principles of electrophysiology. Both versions of the STAR Apollo Mapping System software use fixed algorithms and equations to analyze the data sets. Both versions of the STAR Apollo Mapping System software are air gapped and cannot be connected to a network or the internet.

Both versions of the STAR Apollo Mapping Systems assist in the interpretation 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 (v1.8)	**STAR Apollo Mapping System (v1.6)**	**Subject Device to Predicates**
Regulatory			
510(k) No.	K25XXXX	K240509	
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 the interpretation and manual annotation of 3D anatomical and electrical maps of human atria using data from multipolar, intracardiac, atrial,	STAR Apollo™ Mapping System assists users in manual annotation of 3D anatomical and electrical maps of human atria using data from multipolar, intracardiac, atrial,	Identical

	SUBJECT DEVICE	PRIMARY PREDICATE	COMPARISON
	STAR Apollo Mapping System (v1.8)	**STAR Apollo Mapping System (v1.6)**	**Subject Device to Predicates**
	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.	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.	
Intended Use Population	Individuals undergoing EP procedures	Individuals undergoing EP procedures	Identical
Intended Use Environment	Clinical and hospital environment	Clinical and hospital environment	Identical
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 using an external portable storage device or ethernet connection into the STAR Apollo Mapping System software. The STAR Apollo Mapping System performs calculations and computations using	The physician transfers the export data using an external portable storage device into the STAR Apollo Mapping System software. The STAR Apollo Mapping System performs calculations and computations using the input data. The	Identical

	SUBJECT DEVICE	PRIMARY PREDICATE	COMPARISON
	STAR Apollo Mapping System (v1.8)	**STAR Apollo Mapping System (v1.6)**	**Subject Device to Predicates**
	the input data. The STAR Apollo Mapping System displays a graphical representation of the anatomy of the heart atrial chamber overlaid with the Early Sites of Activation (ESA) and Repetitive Patterns of Activation (RPA) for atrial fibrillation. WaveTrail is displayed as a color map overlaid on the cardiac geometry.	STAR Apollo Mapping System displays a graphical representation of the anatomy of the heart atrial chamber overlaid with the Early Sites of Activation (ESA) and Repetitive Patterns of Activation (RPA) for atrial fibrillation. WaveTrail is displayed as a color map overlaid on the cardiac geometry.	
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.	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.	Identical The locations of interest of both the subject device and the predicate device are identical 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 Sites of Activation (ESA) and Repetitive Activation Patterns (RPA) using stable contact multipolar catheter recording during atrial fibrillation to provide insights of atrial	The STAR Apollo Mapping System displays graphical representation of the anatomy of a heart chamber overlaid with Early Sites of Activation (ESA) and Repetitive Activation Patterns (RPA) using stable contact multipolar catheter recording during atrial fibrillation to provide insights of	Identical Both STAR Apollo Mapping Systems provide 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 (v1.8)	**STAR Apollo Mapping System (v1.6)**	**Subject Device to Predicates**
	fibrillation. WaveTrail is displayed as a color map overlaid on the cardiac geometry.	atrial fibrillation. WaveTrail is displayed as a color map overlaid on the cardiac geometry.	
System Type	Signal processing-based atrial mapping system	Signal processing-based atrial mapping system	Identical Both STAR Apollo Mapping Systems have Graphic User Interface (GUI) and the ability to receive export data from the LiveSync via ethernet connection from Ensite X EP System.
Display(s)	Color Monitor	Color Monitor	Identical
Control	Laptop mouse/touchscreen	Laptop mouse/touchscreen	Identical
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	Displays visual cues after analyzing intracardiac atrial electrograms using signal processing techniques	Identical

	SUBJECT DEVICE	PRIMARY PREDICATE	COMPARISON
	STAR Apollo Mapping System (v1.8)	**STAR Apollo Mapping System (v1.6)**	**Subject Device to Predicates**
Map Types Generated	ESA and RPA displayed on the cardiac geometry. WaveTrail color map is displayed.	ESA and RPA displayed on the cardiac geometry. WaveTrail color map is displayed.	Identical
Compatible Catheters	Advisor HD Grid Mapping Catheter, Sensor Enabled (K172393) Advisor HD Grid X Mapping Catheter, Sensor Enabled (K24106) OPTRELL™ Mapping Catheter with TRUEref™ (K230253)	Advisor HD Grid Mapping Catheter, Sensor Enabled (K172393) Advisor HD Grid X Mapping Catheter, Sensor Enabled (K24106)	Similar STAR Apollo Mapping System (v1.6) is compatible with both HD Grid and HD Grid X mapping catheters. STAR Apollo Mapping System (v1.8) is compatible with both HD Grid and HD Grid X mapping catheters and the OPTRELL Mapping Catheter with TRUEref.
Compatible System	Ensite Precision Cardiac Mapping System Model EE 3000 (V2.6) (K201148) Ensite X EP System (V 1.1.1, V 2.0, V 3.0, V 3.1) (K213364)(K221213) (K231415)(K242016) including LiveSync module. CARTO™ 3 EP Navigation System V8.1 (K252302)	Ensite Precision Cardiac Mapping System Model EE 3000 (V2.6) (K201148) Ensite X EP System (V 1.1.1, V 2.0, V 3.0, V 3.1) (K213364)(K22121) (K231415) not using LiveSync.	Similar STAR Apollo Mapping System (v1.6) is compatible with Ensite X EP System (V 3.1) which is compatible with the HD Grid X mapping catheter. STAR Apollo Mapping System (v1.8) is compatible with Ensite X EP System (V 3.1) which is compatible with the HD Grid X mapping catheter and the CARTO™ 3 EP Navigation System V8.1 with is compatible with the OPTRELL Mapping Catheter with TRUEref Technology.
Hardware Design and Materials Used	Off-the Shelf information technology (IT) hardware: Laptop computer and screen, connection cable, acquisition USB,	Off-the-shelf information technology (IT) hardware: computer and monitor, connection cable, acquisition system,	Identical

	SUBJECT DEVICE	PRIMARY PREDICATE	COMPARISON
	STAR Apollo Mapping System (v1.8)	**STAR Apollo Mapping System (v1.6)**	**Subject Device to Predicates**
	proprietary software algorithm	proprietary software algorithm	

8) CONCLUSION

The STAR Apollo Mapping System software (v1.8) and its predicate STAR Apollo Mapping System (v1.6) both work with US FDA cleared standard electrophysiology mapping systems and catheters to aid in mapping the human atria. The STAR Apollo Mapping System(s) assists operators in the interpretation of anatomical and electrical maps of human atria, using data from multipolar, intracardiac electrograms during atrial fibrillation.

Specifically, the STAR Apollo Mapping System software (v1.8) is substantially equivalent to the STAR Apollo Mapping System software (v1.6). In particular, the STAR Apollo Mapping System (v1.8) performs an equivalent function to the predicate device STAR Apollo Mapping (v1.6) and works with mapping systems and compatible catheters to form a system. Both STAR Apollo Mapping System versions have similar technological characteristics and principles of operation. The STAR Apollo Mapping System software uses the same multipolar electrograms and have the same input (intracardiac atrial data) and have similar output. The STAR Apollo Mapping System software has the same intended use and indications, technological characteristics, and principles of operation as its predicate device. 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 (v1.8) is substantially equivalent and does not introduce any new issues associated with safety and effectiveness.