February 14, 2022

Synaptic Medical Corporation
Charles Yang
Vice President of Quality and Regulatory Affairs
1817 Aston Ave, Suite 101
Carlsbad, California 92008

Re: K203793
Trade/Device Name: RithmID-SD Steerable Diagnostic Electrophysiology Catheter
Regulation Number: 21 CFR 870.1220
Regulation Name: Electrode Recording Catheter Or Electrode Recording Probe
Regulatory Class: Class II
Product Code: DRF
Dated: December 21, 2020
Received: December 28, 2020

Dear Charles Yang:

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 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)*
K203793

Device Name
RithmID-SD Steerable Diagnostic Electrophysiology Catheter

Indications for Use *(Describe)*
The RithmID-SD Steerable Diagnostic Electrophysiology Catheter can be used in the evaluation of a variety of cardiac arrhythmias from endocardial and intravascular sites.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"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."

RithmID-SD Steerable Diagnostic Electrophysiology Catheter
510(k) Summary

This 510(k) Summary for the RithmID-SD Electrophysiology Catheter is submitted in accordance with the requirements of 21 CFR 807.87(h) and 807.92 and following the recommendation outlined in FDA Guidance, *The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notification [510(k)],* dated 28 July, 2014.

SUBMITTER [807.92(a)(1)]

Synaptic Medical Corporation
1817 Aston Ave Suite 101
Carlsbad CA 92008

Contact Person: Charles Yang
Telephone: 760-608-8388
E-mail: Charles.yang@synapticmed.com
Date prepared: January 2, 2022

DEVICE [807.92(a)(2)]

Trade/Device Name:	RithmID-SD Steerable Diagnostic Electrophysiology Catheter
Common/Generic Name:	Diagnostic Electrophysiology Catheter
Regulation Name:	Electrode Recording Catheter
Product Code:	DRF
Regulatory Class:	Class II
Submission Type:	Traditional 510(k)
Regulation Number:	21 C.F.R. 870.1220
Reviewing Product Branch:	Division of Cardiovascular Devices Office of Device Evaluation, CDRH

PREDICATE DEVICE [807.92(a)(3)]

Map-It™ Diagnostic Mapping Catheters (K160390)

REFERENCE DEVICE

Inquiry™ Steerable Diagnostic Catheter (K961924)

DEVICE DESCRIPTION [807.92(a)(4)]

The RithmID-SD Steerable Diagnostic Electrophysiology Catheter are intended to be used in the evaluation of a variety of cardiac arrhythmias from endocardial and intravascular sites. The RithmID-SD Steerable Diagnostic Electrophysiology Catheter are biocompatible, flexible, radiopaque electrophysiology catheters that are available in a variety of diameters, lengths, curve shapes, and electrode number and spacing configurations, with a high-torque shaft with an array of platinum iridium alloy electrodes at the distal tip that can be used for recording electrical signals. The catheter is designed to facilitate the electrophysiological mapping of the heart.

The RithmID-SD Steerable Diagnostic Electrophysiology Catheter consist of a handle, a shaft and a steerable diagnostic tip. The catheter is introduced through the sheath and into the femoral vein, from the inferior vena cava into the heart and coronary sinus. The RithmID-SD Steerable Diagnostic Electrophysiology Catheter are available in 6F in various curves, including B, D, Y, and R curves.

INDICATIONS FOR USE [807.92(a)(5)]

The RithmID-SD Steerable Diagnostic Electrophysiology Catheter can be used in the evaluation of a variety of cardiac arrhythmias from endocardial and intravascular sites.

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS [807.92(a)(6)]

The technological characteristics of the RithmID-SD Steerable Diagnostic Electrophysiology Catheter is highly analogous to the technological characteristics of the Map-It™ Diagnostic Mapping Catheters (Predicate Device, K160390) and Inquiry™ Steerable Diagnostic Catheter (Reference Device, K961924). Substantial equivalence is determined based on the following similarities:

- Same intended use/indications for use
- Same principle of operation
- Same fundamental scientific technology
- Incorporate similar catheter construction material
- Incorporate similar basic catheter design

Table 1 comprises the comparison among RithmID-SD Steerable Diagnostic Electrophysiology Catheter (Subject Device), Map-It™ Diagnostic Mapping Catheters (Predicate Device, K160390), and Inquiry™ Steerable Diagnostic Catheter (Reference Device, K961924)

Table 1: Predicate Device, Reference Device vs. Subject Device Comparison

Feature	[Predicate Device] Map-It™ Diagnostic Mapping Catheters K160390	[Reference Device] Inquiry™ Steerable Diagnostic Catheter K961924	[Subject Device] RithmID-SD Steerable Diagnostic Electrophysiology Catheter
Product Code	DRF	DRF	Same as Predicate Device and Reference Device
Regulatory Class	II	II	Same as Predicate Device and Reference Device
Regulation Number	21 CFR 870.1220	21 CFR 870.1220	Same as Predicate Device and Reference Device
Regulation Name	Electrode Recording Catheter	Electrode Recording Catheter	Same as Predicate Device and Reference Device
Generic Name	Diagnostic Electrophysiology Catheter	Diagnostic Electrophysiology Catheter	Same as Predicate Device and Reference Device
Indications for Use Statement	The APT Map-It™ diagnostic Mapping Catheters can be used in the evaluation of a variety of cardiac arrhythmias from endocardial and intravascular sites.	The Inquiry fixed curve and steerable electrophysiology catheters are used for electrogram recording and cardiac stimulation during diagnostic electrophysiology studies. The catheters are commonly placed at the high right atrium, right ventricular apex, and HIS bundle.	The RithmID-SD Steerable Diagnostic Electrophysiology Catheter can be used in the evaluation of a variety of cardiac arrhythmias from endocardial and intravascular sites.
Intended Use	Intended to facilitate the electrophysiological mapping of the heart.	Intended to facilitate the electrophysiological mapping of the heart.	Same as Predicate Device and Reference Device

Feature	[Predicate Device] Map-It™ Diagnostic Mapping Catheters K160390	[Reference Device] Inquiry™ Steerable Diagnostic Catheter K961924	[Subject Device] RithmID-SD Steerable Diagnostic Electrophysiology Catheter
Component	• Handle • Shaft • Steerable diagnostic tip	Not Listed	• Handle • Shaft • Steerable diagnostic tip
Effective Length	1100 mm	Not Listed	1050 mm
Number of Electrodes	4/5/10/20	Not Listed	4/6/10
French Size	4F/5F/6F/7F	Between 5F and 8F	6F
Outer Diameter	4F, 5F, 6F, 7F Fixed Catheters: 4/3.3F, 4F, 5F, and 6F sizes with a 0.026" guidewire tip configuration	Not Listed	6F
Tip Form	Electrode tip on all models except the guidewire tip and PV loop configuration	Not Listed	Electrode Tip
Ring Electrode Width	0.6mm/1mm/2mm	Not Listed	1.25 mm

Feature	[Predicate Device] Map-It™ Diagnostic Mapping Catheters K160390	[Reference Device] Inquiry™ Steerable Diagnostic Catheter K961924	[Subject Device] RithmID-SD Steerable Diagnostic Electrophysiology Catheter
Configuration	• Cable connector and handle • Pt-Ir Electrodes (4-20), various widths • Shaft 4F to 7F Thermoplastic elastomer • Strain reinforcement shrink tubing • Various Curves	Not Listed	• Cable connector and handle • Pt-Ir Electrodes (4 to 10) • Shaft 6F Thermoplastic elastomer • Strain reinforcement shrink tubing • Various Curves
Material	PEBAX catheter shaft, Platinum-iridium electrodes and electrical connectors	Not Listed	• Shaft (main tube): PEBAX 7033 • Tip Tubing: PEBAX 5533, PEBAX 6333, or PEBAX 4033 • Electrodes (Ring & Tip): Pt/Ir alloy • Adhesive: Loctite 4311
Sterilization	Ethylene Oxide	Ethylene Oxide	Same as Predicate Device and Reference Device
Method of Supply	Sterile and Single Use	Sterile and Single Use	Same as Predicate Device and Reference Device

PERFORMANCE DATA [807.92(b)]

Performance Bench Testing and Animal Testing: Results of the performance bench testing (**Table 2**) indicate that RithmID-SD Steerable Diagnostic Electrophysiology Catheter meets established performance requirements and is substantially equivalent for its intended use.

Table 2: Performance Bench Testing Summary

Performance Bench Testing	
Tests	**Results**
Corrosion Resistance	All test samples met the acceptance criteria.
Particulate Matter Evaluation	All test samples met the acceptance criteria and is equivalent to the Reference Device.
Radiopacity Detectability	All test samples met the acceptance criteria.
Signal Acquisition	All test samples met the acceptance criteria.
Usability	All test samples met the acceptance criteria. The performance of the Subject Device is better or equivalent to the Reference Device.
Electrical Safety	All test samples met the acceptance criteria.
Visual Inspection	All test samples met the acceptance criteria.
Dimensional Verification	All test samples met the acceptance criteria.
Simulated Use	All test samples met the acceptance criteria.
Connection Plug Force	All test samples met the acceptance criteria.
Tip Fatigue Tolerance	All test samples met the acceptance criteria.

Shaft Fatigue Tolerance	All test samples met the acceptance criteria.
Flexural Fatigue Tolerance	All test samples met the acceptance criteria.
Torsional Force	All test samples met the acceptance criteria.
Electrode Conductor Resistance	All test samples met the acceptance criteria.
Buckling Force	All test samples met the acceptance criteria. The buckling force of the Subject Device is less than or equal to the Reference Device.
Peak Tensile Force	All test samples met the acceptance criteria. The peak tensile force of the Subject Device was compared to the Reference Device.
Torque Strength	The average number of 360° rotations when permanent mechanical deformation occurs was recorded for the Subject Device and Reference Device. The torque strength of the Subject device is compared to the Reference Device for reference only.
Packaging Integrity	
Distribution Simulation	All test samples met the acceptance criteria per ASTM D4169-16.
Visual Inspection	All test samples met the acceptance criteria per ASTM F1886/F1886M-16
Bubble Leak Test	All test samples met the acceptance criteria per ASTM F2096-11.
Tray Seal Strength	All test samples met the acceptance criteria per F88/F88M-15.

Biocompatibility: Results of the biocompatibility testing (**Table 3**) indicate that RithmID-SD Steerable Diagnostic Electrophysiology Catheter is biocompatible and is substantially equivalent for its intended use.

Table 3: Biocompatibility Test Summary

Test	Conclusion
Cytotoxicity – MEM Elution Assay ISO 10993-5	Non-cytotoxic
Sensitization - ISO Guinea Pig Maximization (2 Extracts) ISO 10993-10	Non-sensitizer
Intracutaneous Reactivity – ISO Intracutaneous Study in Rabbits (2 Extracts) ISO 10993-10	Non-irritant
Acute Systemic Toxicity – ISO Acute Systemic Toxicity Study in Mice (2 Extracts) ISO 10993-11	Non-Toxic
Systemic Toxicity – ISO Materials Mediated Pyrogenicity in Rabbits ISO 10993-11	Non-Pyrogenic
Hemocompatibility – Hemolysis Assay (Direct and Indirect) ISO 10993-4	Non-Hemolytic
Hemocompatibility – ISO Thrombogenicity in Canine (GLP)	Passed

ISO 10993-4	
Hemocompatibility – Complement Activation SC5b-9 Assay ISO 10993-4	Non-Activator
Hemocompatibility – ISO Partial Thromboplastin Time (PTT) Assay ISO 10993-4	Passed

Shelf life: The accelerated shelf-life testing for RithmID-SD Steerable Diagnostic Electrophysiology Catheter has been conducted (t=1 year accelerated aging) with test results confirmed that all acceptance criteria were met. No new questions of safety or effectiveness were raised. Based on the results, we can conclude that RithmID-SD Steerable Diagnostic Electrophysiology Catheter will perform as intended to the Design Specification. RithmID-SD Steerable Diagnostic Electrophysiology Catheter is labeled for 1-year shelf life.

Packaging: The packaging validation, t=1 year accelerated aging was performed on the RithmID-SD Steerable Diagnostic Electrophysiology Catheter. The results from packaging testing conducted on RithmID-SD Steerable Diagnostic Electrophysiology Catheter showed that the acceptance criteria were met. Therefore, we can conclude the RithmID-SD Steerable Diagnostic Electrophysiology Catheter packaging will provide the adequate and effective protection and sterile barrier requirements.

Sterilization: RithmID-SD Steerable Diagnostic Electrophysiology Catheter is sterilized using 100% Ethylene Oxide (EO) gas in the same manner as FDA cleared Predicate Device, Map-It™ Diagnostic Mapping Catheters (K160390) and Reference Device, Inquiry™ Steerable Diagnostic Catheter (K961924). RithmID-SD Steerable Diagnostic Electrophysiology Catheter is sold sterile, for single use, and single patient only. The sterilization validation results showed that the stylization dose and routine sterilization process was validated to achieve a SAL of 10^{-6} for the RithmID-SD Steerable Diagnostic Electrophysiology Catheter.

.

Test Description	Results
Original Sterilization Validation and Adoption	The validation study demonstrated that the sterilization process and equipment are capable of reliably and consistently sterilizing the device to a minimum SAL of $10^{-6.}$ The sterilization adoption study demonstrated the appropriateness of the ethylene oxide sterilization process for the subject device family. The subject device family was adopted to the original validated sterilization cycle parameters and chambers.
EO and ECH Residuals	The residual traces of EO and ECH for the subject device are below the limits specified in ISO 10993-7.
Bacterial Endotoxin Levels	<20.0 EU/Device

CONCLUSIONS

RithmID-SD Steerable Diagnostic Electrophysiology Catheter met all specified criteria. We conclude that the Subject Device, RithmID-SD Steerable Diagnostic Electrophysiology Catheter, is substantially equivalent in its intended use, design, material, performance, and the underlying fundamental scientific technology used, to the Predicate Device, Map-It™ Diagnostic Mapping Catheters (K160390) and the Reference Device, Inquiry™ Steerable Diagnostic Catheter (K961924).