September 6, 2024

Synaptic Medical Corporation
Jake Harandi
Quality and Regulatory Manager
1959 Kellogg Avenue
Carlsbad, California 92008

Re: K233900
Trade/Device Name: Nordica PV Cryo Mapping Catheter
Regulation Number: 21 CFR 870.1220
Regulation Name: Electrode Recording Catheter Or Electrode Recording Probe
Regulatory Class: Class II
Product Code: DRF
Dated: August 6, 2024
Received: August 7, 2024

Dear Jake Harandi:

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.

510(k) Number *(if known)*
K233900

Device Name
Nordica PV Cryo Mapping Catheter

Indications for Use *(Describe)*
The Nordica PV Cryo Mapping Catheter is indicated for multiple electrode electrophysiological mapping of cardiac structures (i.e., recording and stimulation only). The Nordica PV Cryo Mapping Catheter is designed to obtain electrograms in the atrial regions of the heart.

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."

510(k) SUMMARY

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of 21 CFR 807.92:

I. SUBMITTER

Manufacturer:	Synaptic Medical Corporation 1959 Kellogg Avenue Carlsbad, CA 92008, USA Office Phone: +1-760-608-8388
Contact Person:	Jake Harandi Quality & Regulatory Manager Synaptic Medical Corporation
Email:	jake.harandi@synapticmed.com
Direct Phone:	+1-661-345-1199

Date Prepared:	September 4, 2024

II. DEVICE

Device Trade Name:	Nordica PV Cryo Mapping Catheter
Common Name:	Catheter, Electrode Recording, Or Probe, Electrode Recording
Classification Name:	Electrode Recording Catheter
Regulation:	21 CFR 870.1220
Regulatory Class:	Class II
Review Panel:	Cardiovascular
Product Classification Code:	DRF

III. PREDICATE DEVICE

Predicate Manufacturer:	Medtronic, Inc.
Predicate Trade Name:	Achieve Advance Mapping Catheter
Predicate 510(k):	K162892

IV. DEVICE DESCRIPTION

The Nordica PV Cryo Mapping Catheter is a 3F sterile, single use, multi-electrode, diagnostic catheter designed to map cardiac signals during ablation procedures. The catheter is provided with a fixed loop diameter of 15mm or 20mm with either 5 or 4 evenly spaced, radiopaque pairs of electrodes. The proximal end of the catheter contains an electrical connection for the EP electrical cable that integrates with electrophysiology lab recording systems. Once deployed in the vasculature through the central lumen of a catheter, a circular or spiral shape is established such that the electrodes contact the endocardial surface. This allows for recording, pacing, and interrogation of electrical conduction between the left atrium and the pulmonary veins.

V. INDICATIONS FOR USE

The Nordica PV Cryo Mapping Catheter is indicated for multiple electrode electrophysiological mapping of cardiac structures (i.e., recording and stimulation only). The Nordica PV Cryo Mapping Catheter is designed to obtain electrograms in the atrial regions of the heart.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVCE

The subject and predicate devices have the same intended use and indications for use and utilize the same fundamental scientific technology and principles of operation.

Table 1 provides a comparison of the subject and predicate devices technological characteristics.

TABLE 1: COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE			
Feature	**Subject Device: Synaptic Medical Corporation, Nordica PV Cryo Mapping Catheter**	**Predicate Device: Medtronic, Inc., Achieve Advance Mapping Catheter (K162892)**	**Rationale for Substantial Equivalence**
Product Code	DRF	DRF	Same Product Code as Predicate Device.
Regulation	21 CFR 870.1220	21 CFR 870.1220	Same Regulation Number as Predicate.
Indications for Use	The Nordica PV Cryo Mapping Catheter is indicated for multiple electrode electrophysiological mapping of cardiac structures (i.e., recording and stimulation only). The Nordica PV Cryo Mapping Catheter is designed to obtain electrograms in the atrial regions of the heart.	The Achieve Advance mapping catheter is indicated for multiple electrode electrophysiological mapping of the cardiac structures of the heart, i.e. recording or stimulation only. The Achieve Advance mapping catheter is designed to obtain electrograms in the atrial regions of the heart.	Same Indications for Use as Predicate Device.
Intended Use	The intended use of the Nordica PV Cryo Mapping Catheter is to map intracardiac structures of the heart.	The intended use of the Achieve Advance Mapping Catheter is to map intracardiac structures of the heart.	Same Intended Use as Predicate Device.
Sterilization	Ethylene Oxide Sterilized	Ethylene Oxide Sterilized	Same Sterilization Method as Predicate Device
Single Use	Yes	Yes	Same Single Use as Predicate Device.
Biocompatibility	Complies with ISO 10993-1	Complies with ISO 10993-1 as specified in predicate K153139	Same Biocompatibility compliance as Predicate Device – subject device complies to current revision of the standard.
Performance	Per ISO 10555-1:2013/AMD 1:2017	Per ISO 10555-1	Same Performance standards as Predicate Device – subject device complies to current revision of the standard.

TABLE 1: COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE			
Feature	**Subject Device: Synaptic Medical Corporation, Nordica PV Cryo Mapping Catheter**	**Predicate Device: Medtronic, Inc., Achieve Advance Mapping Catheter (K162892)**	**Rationale for Substantial Equivalence**
Design Features	Outer Diameter: 3F (1mm)	Outer Diameter: 3F (1mm)	Same Outer Diameter size as predicate device.
	Effective Length: 149 cm	Effective Length: 146 cm	The subject device has equivalent effective length compared to predicate device. The effective length of the subject device has demonstrated compatibility with Synaptic catheters and safe and effective use through V&V studies.
	Distal End Shape: Circular Loop	Distal End Shape: Circular Loop	Same Distal End Shape as predicate device.
	Loop Diameter: 15mm & 20mm	Loop Diameter: 15mm & 20mm (K162892) 25 mm (K153139)	Same Loop Diameters as predicate device.
	Number of Electrodes: 8 (15mm loop) 10 (20mm loop)	Number of Electrodes: 8 (15mm loop) 8 (20mm loop) 10 (25mm loop)	Same number of electrodes as predicate device.
	Electrode Spacing: Paired Electrodes, Spacing Between Pairs 7.3 mm (15mm loop/8 electrodes) 7.3mm (20mm loop/10 electrodes) Paired Electrodes, Spacing Between Electrodes 2 mm (15mm and 20mm loops)	Electrode Spacing: Unpaired, Spacing Between Electrodes 4.1mm (15mm loop) 5.8mm (20mm loop) 5.8mm (25mm loop)	Similar electrode spacing to predicate device. Differences in spacing are due to the paired electrodes implemented for the subject device. The paired electrodes have demonstrated safety and performance through V&V testing.

TABLE 1: COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE			
Feature	**Subject Device:** **Synaptic Medical Corporation,** **Nordica PV Cryo Mapping Catheter**	**Predicate Device: Medtronic, Inc.,** **Achieve Advance Mapping Catheter** **(K162892)**	**Rationale for** **Substantial Equivalence**
	Delivered Through a Delivery Catheter: Yes	Delivered Through a Delivery Catheter: Yes	Same delivery method as predicate device.
Materials	Catheter Body Tubing: Nitinol / Pebax (Distal Body) Stainless Steel (Proximal)	Catheter Body Tubing: Nitinol / Pebax (Distal Body) Stainless Steel / Polyimide (Proximal)	The subject and predicate devices are constructed of equivalent materials. Any differences have been qualified through biological safety and V&V testing.
	Loop Material: Nitinol covered with Pebax	Loop Material: Nitinol insulated with PET (Pebax Covered)	
	Electrode Material: 90% Platinum / 10% Iridium	Electrode Material: Not Specified	
	Tip: Loctite 4311 Medical Grade Adhesive	Tip: Not Specified	
Performance Testing	Thermal Conditioning & Packaging Distribution per ASTM D4332-22 and ASTM D4169-22	Thermal Conditioning & Packaging Distribution TT0224 (per ASTM 4332 and D4169)	Same as predicate device – testing for subject device performed in accordance with latest versions of standards.
	Performance Testing per ISO 10555-1: • Dimensional • Atraumatic Tip & Surface • Joint Strength / Peak Tensile Force • Corrosion Resistance • Radiopacity (verified in GLP animal study)	Performance Testing per ISO 10555-1: • Joint Strength • Corrosion Resistance (K153139) • Radiopacity	Same as predicate device – testing for subject device performed in accordance with latest versions of standards. Requirements established for these tests were validated for their intended use through V&V testing.
	Device Specific Performance Testing: • Radial Loop Compliance • Distal Stiffness • Axial Load • Torque Response • Electrical Continuity • Turns to Failure	Device Specific Performance Testing: • Radial Loop Compliance • Distal Stiffness • Axial Load • Torque Response • Electrical Continuity • Turns to Failure	Same as predicate device. Requirements established for these tests were validated for their intended use through V&V testing.

TABLE 1: COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE			
Feature	**Subject Device:** **Synaptic Medical Corporation,** **Nordica PV Cryo Mapping Catheter**	**Predicate Device: Medtronic, Inc.,** **Achieve Advance Mapping Catheter** **(K162892)**	**Rationale for** **Substantial Equivalence**
	• Device Functionality • Kink Resistance • Stiffness • Life Testing	• Device Functionality • Kink Resistance • Stiffness • Life Testing	

VII. PERFORMANCE DATA

The following performance data were provided in support of the substantial equivalence determination.

Sterilization Testing

The subject device and predicate device are both sterilized by Ethylene Oxide (EO).

The sterilization process for the subject device was developed and validated in accordance with ISO 11135:2014+A1:2019 (Sterilization of health-care products - Ethylene oxide - Requirements for the development, validation, and routine control of a sterilization process for medical devices).

The results of the validation provided in this submission demonstrate the sterilization process is capable of:

- Achieving a sterility assurance level (SAL) of 10^{-6} or better
- Physically conforming to the required specifications throughout the load for the duration of the sterilization process

Additionally, bioburden was assessed in accordance with ISO 11737-1 and met the acceptance criteria. LAL testing was conducted in accordance with ANSI/AAMI ST72:2009 and FDA Guidance for Industry "Pyrogen and Endotoxin Testing: Questions and Answers." All samples met requirements of less than 0.5 EU/mL or 20.0 EU/device.

EO and ECH Residual testing was conducted for the subject device and demonstrated the sterilized product results in residuals below the limits specified in EN ISO 10993-7:2008 + A1:2022.

Shelf-Life Testing

Shelf-life testing was performed for the subject device by conducting accelerated aging studies in accordance with ASTM F1980-21. Package Integrity testing including label inspection, bubble leak testing per ASTM F2096-11(2019), seal visual inspection, and seal strength testing per ASTM F88/F88M-21 were performed after accelerated aging to confirm sterile barrier shelf-life. Product V&V was performed after accelerated aging to confirm product safety and performance through shelf-life.

Biocompatibility Testing

The subject device is manufactured from equivalent materials as the predicate device and complies with the same biocompatibility requirements of ISO 10993-1.

Biological evaluation was performed in accordance with ISO 10993-1:2018 and FDA's September 4, 2020, Guidance Document - Use of ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process".

When used as intended the subject device will be in contact with circulating blood and/or cardiac tissue for a cumulative exposure of less than 24 hours. Therefore, the device is categorized as Externally Communicating Device, Circulating Blood with Limited Exposure. Biological evaluation included assessment of relevant endpoints for this patient contact categorization including conducting the following tests:

- ISO MEM Elution using L-929 Mouse Fibroblast Cell (ISO 10993-5)
- ASTM Hemolysis – Direct Contact and Extract Method (ISO 10993-4)
- SC5b-9 Complement Activation Assay (ISO 10993-4)
- ASTM Partial Thromboplastin Time (PTT (ISO 10993-4)

- In-Vivo Thrombogenicity Evaluation [GLP Animal Study] (ISO 10993-4)
- ISO Guinea Pig Maximization Sensitization Test (ISO 10993-10)
- ISO Intracutaneous Study in Rabbits (ISO 10993-23)
- ISO Material Mediated Pyrogen Study (GLP) (ISO 10993-11)
- ISO Acute Systemic Toxicity Study in Mice (ISO 10993-11)

All tested subject devices met the acceptance criteria for each biological endpoint test and demonstrated robust biocompatibility in accordance with ISO 10993-1.

Non-Clinical Testing Summary – Benchtop Studies

The following benchtop testing was provided to demonstrate substantial equivalence with the predicate device:

- Visual & Dimensional Inspection
- Buckle Force Testing
- Catheter Deflection in Sheath Testing
- Catheter Shaft Bending & Kink Resistance Testing
- Simulated Use & Compatibility Testing for Intended Use in Anatomical Model
- Connector Axial Strength
- Continuity and Electrical Short Testing
- Peak Tensile Force & Bond Strength Testing

The results of benchtop testing demonstrated the design outputs of the subject device met the design input acceptance criteria required to demonstrate substantial equivalence with the predicate device.

Software Verification and Validation Testing

This section is not applicable as the subject and predicate devices do not contain any software components or utilize software for their intended use.

Electrical safety and electromagnetic compatibility (EMC)

The Nordica PV Cryo Mapping Catheter complies with the following:

- All applicable EMC requirements of: IEC 60601-1-2 Ed. 4.1 (2020-09) for Class A for Emissions (Professional Healthcare Facility Environment).
- All applicable basic safety and essential performance requirements of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012, IEC 60601- 1:2005/AMD2:2020.
- All applicable usability requirements of IEC 60601-1-6:2010, AMD1:2013, AMD2:2020 for use in conjunction with IEC 62366-1:2015, AMD1:2020, and IEC 60601-1:2005, AMD1:2012, AMD2:2020.

Pre-Clinical Testing Summary – GLP Animal Study

A chronic GLP animal study was performed to validate the chronic safety, performance, and usability of the subject device when used in a canine animal model according to its intended use (intended use of subject device is identical to the predicate device). The results of the GLP canine study demonstrated the subject device can safely perform its intended use required to demonstrate substantial equivalence.

Human Clinical Performance Testing

Clinical testing was not required to demonstrate substantial equivalence to the predicate device.

VIII. CONCLUSIONS

Extensive non-clinical and pre-clinical testing has been performed on the Nordica PV Cryo Mapping Catheter to evaluate the substantial equivalence of the subject device. The data presented in this submission demonstrates that the subject device is substantially equivalent to the predicate device in regards to device design, materials, and intended use.