February 16, 2024

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

Re: K233708
Trade/Device Name: NaviGo 12F Steerable Intracardiac Catheter Introducer Kit (S12FS-01)
Regulation Number: 21 CFR 870.1340
Regulation Name: Catheter Introducer
Regulatory Class: Class II
Product Code: DYB
Dated: November 20, 2023
Received: November 20, 2023

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.

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,

Katherine N. Trivedi -S

for Rachel Neubrander
Director
DHT2B: Division of Circulatory Support,
Structural and Vascular Devices
OHT2: 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)*
K233708

Device Name
NaviGo 12F Steerable Intracardiac Catheter Introducer Kit (S12FS-01)

Indications for Use *(Describe)*
The NaviGo 12F Steerable Intracardiac Catheter Introducer Kit is intended to introduce various cardiovascular catheters into the heart, including the left side of the heart through the interatrial septum.

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.

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510(k) SUMMARY

This summary of 510(k) substantial equivalence information is submitted in accordance with the requirements of 21 CFR 807.92:

K233708

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:	February 16, 2024

II. DEVICE

Device Trade Name:	NaviGo 12F Steerable Intracardiac Catheter Introducer Kit
Common Name:	Introducer, Catheter
Classification Name:	Catheter Introducer
Regulation:	21 CFR 870.1340
Regulatory Class:	Class II
Review Panel:	Cardiovascular
Product Classification Code:	DYB

III. PREDICATE DEVICE

Predicate Manufacturer:	Synaptic Medical Limited
Predicate Trade Name:	Steerable Intracardiac Catheter Introducer Kit and Transseptal Needle
Predicate 510(k):	K151936

IV. DEVICE DESCRIPTION

The NaviGo 12F Steerable Intracardiac Catheter Introducer Kit consists of a 1) Steerable Sheath, 2) Dilator and 3) Guidewire, and is indicated for introducing various cardiovascular catheters into the heart, including the left side of the heart through the interatrial septum. When the left side of the heart is accessed, the device is used with a compatible Transseptal Needle to puncture the interatrial septum for transseptal catheterization procedures.

The NaviGo 12F Steerable Intracardiac Catheter Introducer Kit is a sterile, single use device, with asymmetrical bi-directional steerable introducer with usable length of 65cm. The Steerable Sheath is fitted with a hemostasis valve to minimize blood loss during catheter introduction and/or exchange. A side port

with three-way stopcock is provided for air or blood aspiration, fluid infusion, blood sampling, and pressure monitoring. The handle is equipped with a rotating collar to deflect the Steerable Sheath tip clockwise ≥ 180° and counterclockwise ≥ 90°. The steerable introducer features distal vent holes to facilitate aspiration and a radiopaque tip marker to improve fluoroscopic visualization.

V. INDICATIONS FOR USE

The NaviGo 12F Steerable Intracardiac Catheter Introducer Kit is intended to introduce various cardiovascular catheters into the heart, including the left side of the heart through the interatrial septum.

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. The purpose of this submission is to introduce a 12F version of the 8.5F predicate device to be compatible with various cardiovascular catheters up to 12F diameter.

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**	**Predicate Device (K151936)**	**Rationale for Substantial Equivalence**
Product Code	DYB	DYB	Same Product Code as Predicate Device.
Regulation	21 CFR 870.1340	21 CFR 870.1340	Same Regulation Number as Predicate.
Indications for Use	The NaviGo 12F Steerable Intracardiac Catheter Introducer Kit is intended to introduce various cardiovascular catheters into the heart, including the left side of the heart through the interatrial septum.	The Steerable Intracardiac Catheter Introducer Kit is intended to introduce various cardiovascular catheters into the heart, including the left side of the heart through the interatrial septum.	Same Indications for Use as Predicate Device.
Intended Use	The NaviGo 12F Steerable Intracardiac Catheter Introducer Kit is intended to introduce various cardiovascular catheters into the heart, including the left side of the heart through the interatrial septum.	The Steerable Intracardiac Catheter Introducer Kit is intended to introduce various cardiovascular catheters into the heart, including the left side of the heart through the interatrial septum.	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.
Shelf Life	6-months	3-years	The subject device does not exceed the shelf life of the predicate. The 6-month shelf life of the subject device is qualified by accelerated aging shelf-life studies. The shelf-life of the subject device may be extended at a later time upon completion of additional shelf-life studies.
Biocompatibility	Complies with ISO 10993-1	Complies with ISO 10993-1	Same Biocompatibility compliance as Predicate Device – subject device complies to current revision of the standard.
Performance	Per ISO 11070:2014/AMD 1:2018	Per ISO 11070:1998	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**	**Predicate Device (K151936)**	**Rationale for Substantial Equivalence**
Design Features	Steerable Sheath Introducer Tip	Steerable Sheath Introducer Tip	Same as predicate device. Both devices have radiopaque tip markers and vent holes.
	Curl at Sheath Introducer Tip	Curl at Sheath Introducer Tip	Same as predicate device. Both devices have the same asymmetrical bi-directional deflection, clockwise ≥ 180° and counterclockwise ≥ 90°
	Radiopaque	Radiopaque	Same as predicate. Both devices met radio-detectability requirements per ISO 11070.
	Compatible with Synaptic Medical Limited Transseptal Needles	Curve at Transseptal Needle Tip	The subject device is not supplied with an accessory needle; however, the subject device is designed to be compatible with existing market cleared Synaptic Limited Transseptal Needle models N18980A and N1890E (K132943). Compatibility has been demonstrated through V&V testing.
	0.032" J Curved (Radius: 3mm) Guidewire	0.032" J Curved (Radius: 3mm) Guidewire	The subject device is packaged with the identical J Shape Guidewire as the predicate (K132943). The guidewire used in both the subject and predicate devices is also separately 510(k) cleared for use as a cardiovascular guidewire by Lake Region (K935170). Compatibility has been demonstrated through V&V testing.
Materials	<u>Sheath Introducer</u> • Vestamid Care ML21 Polyamide • PTFE Liner • Pebax 3533/6333/7233 SA01 MED • Barium sulfate radiopaque additive • 304 L Stainless Steel Marker Band • ABS Hemostasis Valve Shelf • Silicone Rubber Hemostasis Valve • Polycarbonate 3-way stopcock • Polyurethane side-arm	<u>Sheath Introducer</u> • HDPE • PTFE Liner • Pebax 2533/3533/5533/7233 SA01 MED • Barium sulfate radiopaque additive • 304 L Stainless Steel Marker Band • ABS Hemostasis Valve Shelf • Silicone Rubber Hemostasis Valve • Polycarbonate 3-way stopcock • Polyurethane side-arm	<u>Sheath Introducer</u> • The subject and predicate devices are constructed of equivalent materials. Any differences have been qualified through biological safety and V&V testing. <u>Dilator</u> • The subject and predicate devices are constructed of equivalent materials. Any differences have been qualified through biological safety and V&V testing.

TABLE 1: COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE			
Feature	**Subject Device**	**Predicate Device (K151936)**	**Rationale for Substantial Equivalence**
	Dilator • LDPE Dilator Tube • Barium sulfate and Titanium Dioxide radiopaque additives • ABS Dilator Hub Guidewire • 304L Stainless Steel • PTFE Coating	Dilator • HDPE Dilator Tube • Bismuth Subcarbonate radiopaque additive • ABS Dilator Hub Guidewire • 304L Stainless Steel • PTFE Coating	Guidewire • The subject device is packaged with the identical J Shape Guidewire as the predicate (K132943). The guidewire used in both the subject and predicate devices is also separately 510(k) cleared for use as a cardiovascular guidewire by Lake Region (K935170). Compatibility has been demonstrated through V&V 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).

To determine the natural bioburden of the sterilized product, bioburden testing was performed in accordance with ISO 11737-1for the subject device as part of the sterilization validation.

To demonstrate implemented microbiological controls are effective at preventing bacterial endotoxins on the sterilized product, LAL testing was performed in accordance with ANSI/AAMI ST72:2019 and FDA Guidance for Industry “Pyrogen and Endotoxins Testing: Questions and Answers.”

Validation of the Kinetic-Turbidimetric LAL Procedure as an End-Product Endotoxin Test has been performed for the subject device for routine monitoring as part of the sterilization release process.

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
- Freedom from Leakage 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.

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.

The primary objective of the GLP animal study was to demonstrate the overall safety of the subject device when used in a pulmonary vein isolation (PVI) procedure in a canine model. The secondary objective was to assess the performance and usability of the subject device in the canine model.

The study simulated a clinical pulmonary vein isolation (PVI) procedure using six (6) healthy canines. The subject device was used to navigate an ablation catheter and pulmonary vein diagnostic catheter to a minimum of two (2) pulmonary veins (PV) in each canine.

Two (2) Board Certified Electrophysiologists specializing in ablation of pulmonary veins in the management of atrial fibrillation performed the procedures and rated the overall performance and usability of the subject device. At the end of the procedure all devices were removed, and a thrombogenicity assessment was completed.

Overall, the GLP animal study demonstrated that the subject device can be safely and effectively used for its intended use.

Additionally, performance and usability evaluation of the subject device in the canine model met the acceptance criteria with predominant rating of Acceptable and Above Average.

VIII. CONCLUSIONS

The data presented in this submission demonstrate that the subject device is substantially equivalent to the predicate device.