August 23, 2024

BioCardia
Peter Altman
President and CEO
320 Soquel Way
Sunnyvale, California 94085

Re: K242169
Trade/Device Name: Morph DNA Steerable Introducer Sheath
Regulation Number: 21 CFR 870.1340
Regulation Name: Catheter Introducer
Regulatory Class: Class II
Product Code: DYB
Dated: July 23, 2024
Received: July 24, 2024

Dear Peter Altman:

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,

Misti L. Malone -S

Misti Malone, PhD
Assistant Director
DHT2C: Division of Coronary and
Peripheral Intervention 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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K242169

Device Name

Morph DNA Steerable Introducer Sheath

Indications for Use *(Describe)*

The Morph DNA Steerable Introducer Sheath is intended to provide a pathway through which medical instruments, such as balloon dilatation catheters, guidewires, or other therapeutic devices, may be introduced into the peripheral vasculature or chambers and coronary vasculature 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 summary of 510(k) is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

Date Prepared: July 15, 2024

510(k) number: K242169

Applicant Information:
BioCardia, Inc.
320 Soquel Way
Sunnyvale, CA 94085

Contact Person
Edward Gillis
Sr. VP of Devices
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Device Information:

Trade Name:	Morph DNA Steerable Introducer Sheath
Classification:	870.1340. - Class II
Classification Name:	Catheter Introducer
Product Code:	DYB

Predicate Device: 8F Morph® DNA Deflectable Guide Catheter	K192774
Reference Device: Avance 8.5 F Steerable Introducer	K190941
Reference Device: BioCardia Morph® Sheath Guide	K090999

Device Description:
The Morph DNA Steerable Introducer Sheath is sterile, single-use bidirectional deflectable catheter with an ergonomic handle that has an integrated swiveling hemostasis valve. When the handle is fully actuated, the distal tip deflects to a nominal angle in either of two directions based on the diameter and the working length of the catheter. The catheter tip includes a fluoroscopic marker to help visualize the tip location and vent holes to facilitate aspiration and flushing of the lumen. The Morph DNA handle includes a brake to hold the deflection angle, an integrated hemostasis valve with a swiveling sideport, and 3-way stopcock.

Devices are packaged with a compatible dilator on a plastic backing card within a sealed Tyvek pouch, all of which are contained in a product box.

Indications for Use:
The Morph DNA Steerable Introducer Sheath is intended to provide a pathway through which medical instruments, such as balloon dilatation catheters, guidewires, or other therapeutic devices, may be introduced into the peripheral vasculature or chambers and coronary vasculature of the heart.

Comparison of Technological Characteristics with the Predicate Device:

The Morph DNA Steerable Introducer Sheath is substantially equivalent to the predicate with respect to the following attributes:

- Intended use
- Classification (870.1250. - Class II)
- Basic Design
- Fundamental Technology
- Method of operation
- Inner PTFE lining with external Pebax extrusion jacket
- Rocker mechanism in handle for deflecting catheter tip via pull wire tensioning.
- Catheter mounted onto inner backer card, sealed by Tyvek pouch, and enclosed in product box
- Sterilization via Ethylene Oxide
- Compliance with ISO 10993
- Compliance with ISO 10555
- Compliance with ISO 11070
- Compliance with ISO 11135

The specific design differences between Morph DNA Steerable Introducer Sheath and the predicate and reference devices are the following:

- Addition of 7.5F (inner diameter) sizes vs. 5.5F (Morph DNA Deflectable Guide), 8.5F (Avance) and 6.5F (Morph Sheath Guide)
- Additional working length of 30cm vs. 115cm (Morph DNA Deflectable Guide),71cm (Avance), and 45 cm and 90 cm Morph Sheath Guide
- Minor difference in the dilator, where subject product utilizes straight dilator vs. no dilator in Morph DNA Deflectable Guide and pre-curved tip dilator in Avance. Morph Sheath Guide similarly uses a straight dilator.
- The maximum tip deflection is greater than predicate and reference devices in shorter lengths.
- The range for distal curvature is greater than predicate and reference devices.

Supporting Data/Information:

Performance

The following tests were conducted to confirm that the modifications made between the Morph DNA Steerable Introducer Sheath and predicate/reference devices did not affect the ability to meet all product specification requirements.

In-Vitro Bench Top Testing
Distal Tip – right/left deflection angle, curve distance, residual curvature in neutral position, angular deviation from plane
Catheter Dimensional Verification – inner diameter, outer diameter, working length
Catheter and Handle Functionality – Freedom from leakage, dilator and HMV connections, torsional rigidity, bend kink resistance, column support, max actuation force, curve size, deflection angle, deflection mechanism robustness, pullwire tensile strength, brake curve retention, push kink resistance
Fatigue Resistance – Deflection fatigue resistance, torque fatigue resistance
Dilator Verification - Inner diameter, tube joint tensile strength, dilator tube to hub tensile, dilator extension length

Additional testing results applicable for Morph DNA Steerable Introducer Sheath

Packaging Integrity
Atmospheric Conditioning ASTM D4332-14 and Shipping Simulation ASTM D7386-16 Test Schedule 3 – Manual Handling, Random Vibration, Low Pressure Hazard, Tip Over, Rotational Edge Drop, Bridge Impact, Concentrated Impact, Gross Leak (Bubble Test) ASTM F2096-11 Leveraged from Morph DNA predicate and Avance reference devices.

In-Vitro Simulated Use Testing
Catheter Navigation to all intended anatomy
Deflection Mechanism
Brake Mechanism
Device Compatibility to guide therapeutic catheters

Biocompatibility
The materials used in the BioCardia Morph DNA Steerable Introducer Sheath meet the requirements of ISO 10993-1 and FDA guidance, "Use of International Standard ISO 10993-1 – Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process". Results for the following biocompatibility tests were leveraged from the predicate and reference devices:

- Cytotoxicity
- Sensitization
- Irritation
- Acute Systemic Toxicity
- Material Mediated Pyrogenicity
- Hemolysis
- Thromboresistance
- Complement Activation

Sterilization
The Morph DNA Steerable Introducer Sheath was adopted into an existing ethylene oxide sterilization validation for BioCardia products per TIR 28:2009.

Summary:

Based on the intended use, product performance, biocompatibility and sterilization information provided in this notification, the BioCardia Morph DNA Steerable Introducer Sheath has been shown to be substantially equivalent to the predicate.