January 7, 2020

Patrick Lee
Director of Regulatory Affairs
125 Shoreway Road, Suite B
San Carlos, California 94070

Re: K192774
Trade/Device Name: BioCardia 8F Morph DNA Deflectable Guide Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: DQY
Dated: December 10, 2019
Received: December 11, 2019

Dear Patrick Lee:

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,

Rachel Neubrander
Assistant 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K192774

Device Name
8F Morph DNA Deflectable Guide Catheter

Indications for Use *(Describe)*
The biocardia morph universal deflectable guide catheter 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 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.

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"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."

This summary of 510(k) is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

Date Prepared: September 27, 2019

510(k) number: K192774

Applicant Information:

BioCardia, Inc.
125 Shoreway Road, Suite B
San Carlos CA 94070

Contact Person

Patrick Lee
Director of Regulatory Affairs
650-226-0146
Plee@biocardia.com

Device Information:

Trade Name:	8F Morph® DNA Deflectable Guide Catheter
Classification:	870.1250. - Class II
Classification Name:	Percutaneous Catheter
Product Code:	DQY

Predicate Device:

BioCardia Morph Universal Deflectable Guide Catheter K042553

Device Description:

The BioCardia 8F Morph® DNA Deflectable Guide Catheter is a sterile, single use, bi-directional deflectable guide catheter. When the handle is fully actuated, the distal tip deflects to a minimum 135° arc in either of two directions with a nominal curve distance of 30 mm. The catheter tip includes a fluoroscopic marker to help visualize the tip location. The Morph DNA handle includes a brake to hold the deflection angle, an integrated hemostasis valve with a swiveling sideport, and 3-way stopcock.

Indications for Use:

The 8F Morph® DNA Deflectable Guide Catheter 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 Deflectable catheter is identical to the predicate device 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
- 0.071” nominal inner diameter
- 0.104” nominal outer diameter
- Rocker mechanism in handle for deflecting catheter tip via pull wire tensioning.
- Tip deflection curve of 30mm
- 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 and the predicate device are the following:

- Minor differences in catheter shaft construction, where Morph DNA includes an additional braid layer, a bidirectional deflection mechanism, and a distal tip radiopaque marker
- Minor differences in the handle, where Morph DNA includes a brake feature (for adjusting deflection friction) and an integrated hemostasis valve with 3-way stopcock.
- A longer working length of 115cm for Morph DNA vs 110cm for Morph UDGC

Supporting Data/Information:

Performance

The following tests were conducted to confirm that the modifications made between the Morph DNA device and predicate 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, effective length
Catheter Functionality – Freedom from leakage, tension and torsional forces, bend kink resistance, corrosion, column support
Handle Functionality – Actuation force, brake mechanism resisting actuation, brake engagement/disengagement, gradual brake, handle separation force, pull-wire tensile force
Hemostasis Valve – Freedom from leakage, hemostasis valve swivel functionality
Fatigue Resistance – Actuation fatigue resistance, torque fatigue resistance

Package 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.

In-Vivo Simulated Use Testing (Single Swine Model)
Distal Tip Attachment
Radiopaque Marker visible under fluoroscopy
Catheter Navigation to all intended anatomy
Deflection Mechanism
Brake Mechanism
Handle Ergonomics
Device Compatibility to guide therapeutic catheters

Biocompatibility
The materials used in the BioCardia Morph DNA Deflectable Guide Catheter 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”. The following biocompatibility tests were completed:

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

Sterilization
The Morph DNA Deflectable Guide Catheter 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 8F Morph DNA Deflectable Guide Catheter has been shown to be substantially equivalent to the predicate device. We conclude that the BioCardia 8F Morph DNA Deflectable Guide Catheter is as safe and effective as the predicate device described herein.