May 6, 2019

BioCardia, Inc.
℅ Mark Job
Responsible Third Party Official
Regulatory Technology Services, LLC
1394 25th Street, NW
Buffalo, Minnesota 55313

Re: K190941
Trade/Device Name: BioCardia 8.5 F Avance™ Steerable lntroducer
Regulation Number: 21 CFR 870.1340
Regulation Name: Catheter introducer
Regulatory Class: Class II
Product Code: DYB
Dated: April 8, 2019
Received: April 10, 2019

Dear Mark Job:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/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 Nicole G. Ibrahim, Ph.D.
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)*
K190941

Device Name
8.5 F Avance Steerable Introducer

Indications for Use *(Describe)*
The BioCardia 8.5 F Avance Steerable Introducer is intended for introducing 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.

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."

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

Date Prepared: 26 March, 2019

510(k) number: K190941

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

Contact Person
Kevin DeMartini
Sr. Quality Engineer
650-226-0134
kdemartini@biocardia.com

Device Information:

Trade Name:	Avance™ 8.5 F Steerable Introducer
Classification:	870.1340. - Class II
Classification Name:	Catheter Introducer
Product Code:	DYB

Predicate Device:
St. Jude Agilis™ Steerable Catheter Introducer K042623

Device Description:

The BioCardia 8.5 F Avance™ Steerable Introducer (Avance) is a sterile, single use, bi-directional introducer. When the handle is fully actuated, the distal tip deflects to a nominal 180° arc in either of two directions with a nominal curve distance as indicated by the product label. The introducer tip includes a fluoroscopic marker to help visualize the tip location and vent holes to facilitate aspiration and flushing of the lumen. The Avance handle includes a brake to hold the deflection angle, an integrated hemostasis valve with a swiveling sideport, and 3-way stopcock.

Avance includes a dilator with a pre-curved, tapered tip which extends up to 2.5 cm beyond Avance to facilitate transseptal placement. The dilator hub snaps into the Avance hemostasis valve and can accommodate a guidewire diameter of up to .038”.

Indications for Use:
The BioCardia 8.5 F Avance™ Steerable Introducer is intended for introducing various cardiovascular catheters into the heart, including the left side of the heart through the interatrial septum

Comparison of Technological Characteristics with the Predicate Device:
The Avance is the same or substantially equivalent to many geometric specifications, product features, and performance specifications in the predicate Agilis. Avance has minor design differences versus the predicate, such as a rotating versus fixed hemostasis valve, a rocker arm versus a lead screw for creating pull-wire tension and spiraling versus straight pull-wires. The

Avance does not include a guidewire in the product box. These minor differences do not alter the conclusion that the Avance is substantially equivalent to the predicate.

Supporting Data/Information:

Performance
The following tests were conducted to confirm that the design of the Avance meets all product performance requirements:

In-Vitro Bench Top Testing
Distal Tip – right/left deflection angle, curve distance, residual curvature in neutral position, angular deviation from plane
Catheter and Dilator Dimensional Verification – inner diameter, outer diameter, effective length, dilator extension 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, dilator detachment force, 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 Avance Steerable Introducer 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 Avance Steerable Introducer 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 Avance™ Steerable Introducer has been shown to be substantially equivalent to the predicate St. Jude Agilis Steerable Introducer (K042623).