June 30, 2023

Abiomed Inc.
Ken Ryder
Sr. Director, Regulatory Affairs
22 Cherry Hill Drive
Danvers, Massachusetts 01923

Re: K221294
Trade/Device Name: preCARDIA Occlusion System
Regulation Number: 21 CFR 870.4450
Regulation Name: Vascular clamp
Regulatory Class: Class II
Product Code: MJN, DQY, DQO
Dated: May 31, 2023
Received: May 31, 2023

Dear Ken Ryder:

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 and the limitations described below. 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.

The OHT2: Office of Cardiovascular Devices has determined that there is a reasonable likelihood that this device will be used for an intended use not identified in the proposed labeling and that such use could cause harm. Therefore, in accordance with Section 513(i)(1)(E) of the Act, the following limitation must appear in the Warnings and Precautions section of the device's labeling:

1. The safety and effectiveness of this device for use in the treatment of heart failure have not been established.

Furthermore, the indication for use “The preCARDIA device is intended for use in selectively stopping or controlling blood flow of the inferior and superior vena cava in applications including perioperative procedures in patients requiring emergency control of hemorrhage, and for blood pressure monitoring” must be prominently displayed in all labeling, including pouch box, and carton labels, instructions for use, and other promotional materials, in close proximity to the trade name, of a similar point size, and in bold print.

Please note that the above labeling limitations are required by Section 513(i)(1)(E) of the Act. Therefore, a new 510(k) is required before these limitations are modified in any way or removed from the device's labeling.

The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and permits your device to proceed to the market. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification if the limitation statement described above is added to your labeling.

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,

William C. Macfarland -S

Digitally signed by William C. Macfarland -S
Date: 2023.06.30 10:50:45 -04'00'

for Bram Zuckerman, M.D.
Director
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)*
K221294

Device Name
preCARDIA Occlusion System

Indications for Use *(Describe)*
The preCARDIA device is intended for use in selectively stopping or controlling blood flow of the inferior and superior vena cava in applications including perioperative procedures in patients requiring emergency control of hemorrhage, and for blood pressure monitoring.

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."

preCARDIA Occlusion System 510(k) Summary

This summary is being submitted in accordance with the Safe Medical Devices Act (SMDA) of 1990 and Title 21 of the Code of Federal Regulations, Part 807.92.

A. Application Information

Date Prepared:	June 27, 2023
Submitters Name & Address:	ABIOMED, Inc. 22 Cherry Hill Drive Danvers, MA 01923
Contact Person:	J. Kenneth Ryder Senior Director, Global Regulatory Affairs Ph: 978-646-1707 E-mail: kryder@abiomed.com

B. Device Information

Trade or Proprietary Name:	preCARDIA Occlusion System
Regulation Number:	21 CFR 870.4450
FDA Classification:	Class II
Product Code:	MJN, DQY, DQO
Regulation Description:	Vascular Clamp

C. Predicate Device

The predicate device is the NEURESCUE Device (K210358) manufactured by Neurescue Aps. The QXMedical Occlusion Balloon Catheter (K183679) and the CoAxia FloControl Catheter (K090970) serve as reference devices.

The predicate and reference devices have not been subjected to any design-related recall.

D. Device Description:

The preCARDIA System is for use in selectively stopping or controlling blood flow of the inferior and superior vena cava, in applications including perioperative procedures in patients requiring emergency control of hemorrhage, and for blood pressure monitoring. The System includes a Balloon Occlusion Catheter (Catheter), Controller and Console. The Catheter has

an atraumatic endovascular balloon that has been attached to the proximal portion of a commercially available Thermodilution (TD) Catheter. The single use, 110 cm disposable catheter comes in two balloon locations, 34 and 36 cm measured from the distal end of the catheter and is provided sterile. The catheter placement procedure is performed under fluoroscopy by clinicians trained in endovascular techniques. The balloon includes proximal and distal radiopaque markers to allow for visualization and confirmation of proper placement in the IVC or SVC. Following placement and securement of the catheter, the patient can be transferred to the operating room or other appropriate care location where selectively stopping or controlling blood flow in the SVC or IVC will continue alongside other standard of care treatments. The primary operating principle of the preCARDIA System is the selective stopping or controlling of the blood flow in the IVC or SVC through either sustained inflation or successive inflation and deflation cycles of the balloon as regulated by the Controller.

E. Intended Use/Indications for Use:

The preCARDIA device is intended for use in selectively stopping or controlling blood flow of the inferior and superior vena cava in applications including perioperative procedures in patients requiring emergency control of hemorrhage, and for blood pressure monitoring.

F. Technological Characteristics Comparison of Subject and Predicate Devices

A technological characteristics comparison table is provided below.

Feature	Subject Device: preCARDIA Device	Predicate: Neurescue Device	Reference Device: CoAxia FloControl Catheter	Reference Device: QX Medical Occlusion Balloon Catheter
Intended Use	The preCARDIA device is intended for use in selectively stopping or controlling blood flow of the inferior and superior vena cava in applications including perioperative procedures in patients requiring emergency control of hemorrhage, and for blood pressure monitoring.	The Neurescue device is intended for temporary occlusion of large vessels and blood pressure monitoring including patients requiring emergency control of hemorrhaging.	The CoAxia FloControl Catheter is intended for use in selectively stopping or controlling flow in the peripheral vasculature, which includes the descending aorta.	The Occlusion Balloon Catheter is indicated for temporary occlusion of large vessels, including the superior vena cava, in applications including perioperative occlusion and emergency control of hemorrhage.
General System Components	Occlusion Balloon Catheter	Occlusion Balloon Catheter	Occlusion Balloon Catheter	Occlusion Balloon Catheter
Catheter Lumen	10 Fr	7 Fr	7 Fr	8 and 10 Fr
Length	63 and 65 cm working lengths	72 cm	62 cm working length	90 cm shaft length
Occlusion Balloon	32 mm in diameter	30 mm in diameter	32 mm in diameter	36 mm in diameter

Feature	Subject Device: preCARDIA Device	Predicate: Neurescue Device	Reference Device: CoAxia FloControl Catheter	Reference Device: QX Medical Occlusion Balloon Catheter
Balloon	Expandable Polyurethane occlusion balloon and expandable Polyurethane distal floatation balloon	2 expandable Polyurethane balloons separated by 8 cm	Single expandable Polyurethane Balloon	Single expandable Polyurethane Balloon
Controller	Control unit that enables mechanical inflation and deflation of the occlusion balloon as directed by the user	Control unit that enables mechanical inflation and deflation of the occlusion balloon as directed by the user	Manifold hub that enables manual inflation and deflation of the occlusion balloon	Manifold hub that enables manual inflation and deflation of the occlusion balloon
Mechanism of Action, General	Inserted manually using standard techniques. Indwelling (in vessel) after insertion. Occlusion of vessel occurs once initiated by the physician.	Inserted manually using standard techniques. Indwelling (in vessel) after insertion. Occlusion of vessel occurs once initiated by the physician.	Inserted manually using standard techniques. Indwelling (in vessel) after insertion. Occlusion of vessel occurs once initiated by the physician.	Inserted manually using standard techniques. Indwelling (in vessel) after insertion. Occlusion of vessel occurs once initiated by the physician.
Inflation Cycling Capabilities	Manual and Automatic	Manual	Manual	Manual
Marker Bands	2 platinum-iridium marker bands	3 marker bands	3 platinum-iridium markers	1 marker band

The differences between the subject and the predicate devices in terms of technological characteristics do not raise new questions of safety or effectiveness.

G. Performance Testing

The following performance testing was conducted on the preCARDIA Occlusion System.

Bench Testing:

- Visual Inspection and Dimensional Verification
- System Verification
- System Interaction Testing
- User Validation Testing
- Air Leakage Testing
- Liquid Leakage Testing
- Leakage – Tubing Set Testing
- Static Leakage of Occlusion Balloon with Tubing
- Thermistor Testing
- Thermodilution Impact Testing

- Occlusion Balloon Diameter to Filling Volume Test
- Robustness Test of Occlusion Balloon
- Torque and Kink Testing
- Burst Pressure Testing
- Tensile and Peak Tensile Testing
- Crack Pressure Testing
- Pressure Transducer Testing
- Luer-Compliance Testing
- Tensile Strength Testing
- Connector Testing
- Inflation and Deflation Time Testing
- Bend/Kink Resistance Testing
- Radiopacity Testing
- 1-hour Occlusion Testing
- Guidewire Tracking Testing
- Packaging Validation
- Sterilization Validation
- Shelf Life
- Biocompatibility
- Electrical Safety and EMC
- Software Verification and Validation

An animal study to evaluate the performance of the preCARDIA Catheter in the intended anatomy was performed to demonstrate that the device meets applicable design and performance requirements and is therefore substantially equivalent to the predicate device.

H. Conclusions

Performance testing was completed and showed that the subject device, preCARDIA Occlusion System, met the acceptance criteria and demonstrated substantial equivalence.