March 28, 2024

Atrium Medical Corporation
Hannah Scribner
Regulatory Affairs Specialist II
40 Continental Blvd.
Merrimack, New Hampshire 03054

Re: K231972
Trade/Device Name: Advanta VXT Vascular Graft, Flixene Vascular Graft
Regulation Number: 21 CFR 870.3450
Regulation Name: Vascular graft prosthesis
Regulatory Class: Class II
Product Code: DSY
Dated: February 27, 2024
Received: February 28, 2024

Dear Hannah Scribner:

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,

Carmen G. Johnson -S

Carmen Gacchina Johnson, Ph.D.
Assistant Director
DHT2B: Division of Circulatory Support,
Structural and Vascular Devices
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Center for Devices and Radiological Health 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)*
K231972/S001

Device Name
Advanta VXT Vascular Graft, Flixene Vascular Graft

Indications for Use *(Describe)*

Advanta VXT and Flixene vascular grafts are indicated for use in patients with peripheral vascular disease, where peripheral arteries must be repaired or replaced and open surgery is required. Indications for use also includes patients with end stage renal disease requiring arteriovenous vascular access for dialysis.

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.

Atrium Medical Corporation
Premarket Notification Traditional 510(k)
Advanta VXT Vascular Graft
Flixene Vascular Graft

Advanta VXT and Flixene Vascular Grafts 510(k) summary prepared in accordance with 21 CFR part 807.92.

General Information

Submitter's Name and Address	Atrium Medical Corporation 40 Continental Drive Merrimack, NH 03054
Registration Number	3011175548
Contact Person	Hannah Scribner Regulatory Affairs Specialist II Tel: (603) 864-5209 Fax: (973) 629-1325 email: Hannah.scribner@getinge.com
Date Prepared	July 5, 2023

Device Information

Trade Name(s)	Advanta VXT Vascular Grafts Flixene Vascular Grafts
Common/Generic Name(s)	Vascular Graft
Classification Name	Advanta VXT: Prosthesis, Vascular Graft, Of Less Then 6mm Diameter Prosthesis, Vascular Graft, Of 6mm And Greater Diameter Flixene: Prosthesis, Vascular Graft, Of 6mm And Greater Diameter
Regulation Number	21 CFR 870.3450
Product Codes	Advanta VXT: DSY (Prosthesis, Vascular Graft, of 6MM and Greater Diameter) DYF (Prosthesis, Vascular Graft, of less than 6MM Diameter) Flixene: DSY (Prosthesis, Vascular Graft, of 6MM and Greater Diameter)
Device Class	The Advanta VXT and Flixene Vascular Grafts are classified as Class II devices according to 21 CFR 870.3450

Predicate Device Information:

The predicate devices are Atrium Medical Corporation's, Advanta VXT Vascular Graft (K992960: October 01, 1999), Advanta VXT Vascular Graft (K992958: October 01, 1999) and Flixene Vascular Grafts (K071923: August 14, 2007).

Advanta VXT is represented by two (2) predicate 510(k)'s in this submission as K992958 (Product Code: DYF) is specific to grafts 6mm in diameter or less and K992960 (Product Code: DSY) is specific to grafts 6mm in diameter or greater.

The Advanta VXT and Flixene Vascular Grafts, subject of this submission, are substantially equivalent in function and intended use as the predicate devices.

Subject Device Description:

Atrium ePTFE vascular grafts are offered in a variety of designs; (including Advanta VXT and Flixene). They are made primarily of expanded polytetrafluoroethylene (ePTFE), and are available in a wide variety of configurations:

- "Rings" (also referred to as "helix") for added radial support (made from a PTFE monofilament coil)
- The Slider Graft Deployment System consisting of a pre-attached tip(s) with a clear flexible sheath (polyethylene)
- Tapered end
- Thin or standard wall thickness

The Advanta VXT graft is a 2-layer graft employing a single-layer ePTFE graft, which is then wrapped with an additional layer of ePTFE for increased support. The rings available on some Advanta VXT grafts are bonded to the exterior surface of the graft. By following the prescribed procedure, the rings can be removed incrementally as needed. The Flixene vascular graft is a 3-layer graft comprised of ePTFE. This graft was designed with an additional layer of ePTFE. As a result of its design, ring support is not necessary. Implantable portion of graft is comprised of polytetrafluoroethylene (PTFE) with no more than 0.1% cobalt chromite blue-green Spinel ink on

surface of the graft, which is used as a reference line. Additional materials in transient contact during placement of the graft include 303 stainless steel and polyethylene, which represents the graft deployment system and transfer sleeve.

Subject Device Intended Use:

Advanta VXT and Flixene vascular grafts are intended for use in the replacement or repair of peripheral arteries, and for use as an arteriovenous shunt for vascular access.

Subject Device Indication for Use:

Advanta VXT and Flixene vascular grafts are indicated for use in patients with peripheral vascular disease, where peripheral arteries must be repaired or replaced and open surgery is required. Indications for use also includes patients with end stage renal disease requiring arteriovenous vascular access for dialysis.

Intended Use Environment, User/Operator, Patient population, and Intended Use

The following elements are substantially equivalent between the predicate and subject devices.

Table 1 Intended Use Environment, User/Operator, Patient population, and Intended Use

	Predicate Devices Advanta VXT (K992960 and K992958) Flixene (K071923)	**Subject Devices Advanta VXT Flixene**
Intended Use Environment	Surgical Suite	Same as Predicate
Intended User/Operator	They are intended to be implanted by surgeons trained in the theoretical, technical and clinical aspects of vascular reconstruction, bypass and creation of arteriovenous vascular access. Other potential users include dialysis-related nursing staff and clinicians trained in generic vascular access use.	Same as Predicate
Intended Patient Population	Advanta VXT and Flixene vascular grafts are intended for use in adult patients.	Same as Predicate
Intended Use	Advanta VXT and Flixene vascular grafts are intended for use in the replacement or repair of peripheral arteries, and for use as an arteriovenous shunt for vascular access.	Same as Predicate

Figure 1 Vascular Graft Example

Technological characteristics:

Atrium's Advanta VXT and Flixene Vascular grafts, subject of this submission, are technologically different from the predicate devices (K071923, K992960 and K992958) as there are differences in the materials of construction.

Atrium's Advanta VXT and Flixene Vascular grafts, subject of this submission, have the same Device Configuration Options as the predicate devices (K071923, K992960 and K992958).

Major Materials of Construction

The Advanta VXT and Flixene Vascular Grafts, subject of this submission, have different materials of construction then the predicate devices.

Non-clinical Tests

Advanta VXT and Flixene Vascular Grafts comply with the voluntary standards. Atrium Medical's development process required that the following activities be completed during the development of the current configuration of the Advanta VXT and Flixene Vascular Grafts:

Non-Clinical Bench Testing	
Visual Appearance	Water Entry Pressure
Relaxed Internal Diameter	Dynamic Compliance

Non-Clinical Bench Testing	
Pressurized Internal Diameter	Kink Resistance
Wall Thickness	Graft Deployment System Pull Strength
Useable Length	Helix Peel Strength (Advanta VXT only)
Graft Surface Architecture	Wrap Properties
Suture Retention Strength	Material Composition and Construction
Radial Tensile Strength	Modification of Length and/or End
Longitudinal Tensile Strength	Print Legibility
Strength after Repeated Puncture	Shelf-life Validation
Other Non-Clinical Testing	
Sterility Validation	MR Compatibility
Packaging Validation	Biocompatibility Evaluation
Chemical Characterization Analytical Testing	Toxicological Risk Assessment

Clinical Tests

There were no clinical studies of the modified device.

Conclusion

The Advanta VXT and Flixene Vascular Grafts are substantially equivalent to the predicate devices in the fundamental scientific technology of the device. The design verification and validation testing established that the Advanta VXT and Flixene Vascular Grafts are substantially equivalent to the predicate devices.

Based upon the information submitted in this Traditional 510(k) premarket notification, Advanta VXT and Flixene Vascular Grafts subject of this submission are substantially equivalent to the predicate devices Advanta VXT Vascular Graft (K992960 and K992958) and Flixene Vascular Grafts (K071923).