April 17, 2026

Hjarta Care, LLC
Brian Thorson
Founder
N16 W23233 Stone Ridge Drive Suite 200
Waukesha, WI 53188

Re: DEN250033
Trade/Device Name: XplantR Explant Tool
Regulation Number: 21 CFR 870.4520
Regulation Name: Device for open surgical explant of endovascular prostheses
Regulatory Class: Class II
Product Code: SHR
Dated: February 2, 2026
Received: February 3, 2026

Dear Brian Thorson:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your De Novo request for classification of the XplantR Explant Tool, a prescription device under 21 CFR Part 801.109 with the following indications for use:

> The XplantR Explant Tool is indicated for use in open surgical conversion after endovascular abdominal aortic aneurysm repair to aid in the disengagement of the stent graft from the aorta. The XplantR is to be used when, at the discretion of the operating physician, the proximal end of the endovascular graft is to be removed.

FDA concludes that this device should be classified into Class II. This order, therefore, classifies the XplantR, and substantially equivalent devices of this generic type, into Class II under the generic name device for open surgical explant of endovascular prostheses.

FDA identifies this generic type of device as:

> **Device for open surgical explant of endovascular prostheses**. This device is a non-implantable mechanical surgical tool to aid in the open surgical removal of endovascular prostheses in blood vessels.

Section 513(f)(2) of the Food, Drug and Cosmetic Act (the FD&C Act) was amended by section 607 of the Food and Drug Administration Safety and Innovation Act (FDASIA) on July 9, 2012. This law provides two options for De Novo classification. First, any person who receives a "not substantially equivalent" (NSE)

determination in response to a 510(k) for a device that has not been previously classified under the Act may request FDA to make a risk-based classification of the device under section 513(a)(1) of the Act. On December 13, 2016, the 21st Century Cures Act removed a requirement that a De Novo request be submitted within 30 days of receiving an NSE determination. Alternatively, any person who determines that there is no legally marketed device upon which to base a determination of substantial equivalence may request FDA to make a risk-based classification of the device under section 513(a)(1) of the Act without first submitting a 510(k). FDA shall, within 120 days of receiving such a request, classify the device. This classification shall be the initial classification of the device. Within 30 days after the issuance of an order classifying the device, FDA must publish a notice in the Federal Register announcing the classification.

On February 2, 2026, FDA received your De Novo requesting classification of the XplantR. The request was submitted under section 513(f)(2) of the FD&C Act. In order to classify the XplantR into class I or II, it is necessary that the proposed class have sufficient regulatory controls to provide reasonable assurance of the safety and effectiveness of the device for its intended use. After review of the information submitted in the De Novo request, FDA has determined that, for the previously stated indications for use, the XplantR can be classified in class II with the establishment of special controls for class II. FDA believes that class II (special) controls provide reasonable assurance of the safety and effectiveness of the device type. The identified risks and mitigation measures associated with the device type are summarized in the following table:

Identified Risks to Health	**Mitigation Measures**
Vascular or tissue injury	Non-clinical performance testing
Mechanical device failure or malfunction leading to injury, significant blood loss, or inability to aid in endograft explantation	Non-clinical performance testing Shelf life testing Labeling
Inappropriate/incorrect use of the device resulting in patient harm (e.g., vessel injury)	Non-clinical performance testing Labeling
Improper size selection resulting in patient harm (e.g., vessel injury)	Labeling
Adverse tissue reaction	Biocompatibility evaluation
Infection	Sterilization validation Packaging validation Shelf life testing Labeling

In combination with the general controls of the FD&C Act, the device for open surgical explant of vascular prostheses is subject to the following special controls:

(1) Non-clinical performance testing must demonstrate that the device performs as intended under anticipated conditions of use. The following performance characteristics must be tested:
   (i) Characterization and verification of all dimensions;
   (ii) Device integrity;
   (iii) Usability based on simulated use in a clinically relevant model;
   (iv) Compatibility with representative range of devices to be explanted; and
   (v) Corrosion resistance of metallic components.

(2) In vivo performance data must be collected to assess the following:

(i) The ability to safely use the device during the explant procedure;
(ii) The ability to effectively explant the endovascular stent-graft; and
(iii) Device integrity events and any associated clinical sequelae.

(3) All patient-contacting components of the device must be demonstrated to be biocompatible.
(4) Performance data must demonstrate sterility of the device components intended to be provided sterile.
(5) Performance data must support the shelf life of the device by demonstrating continued sterility, package integrity, and device functionality over the identified shelf life.
(6) Labeling for the device must include:
(i) A summary of the device technical parameters;
(ii) Instructions regarding device size selection;
(iii) Identification of available resources for user training;
(iv) A shelf life; and
(v) User expertise in open surgical and endovascular techniques needed for safe use of the device.

In addition, this is a prescription device and must comply with 21 CFR 801.109.

Although this letter refers to your product as a device, please be aware that some granted products may instead be combination products. If you have questions on whether your product is a combination product, contact CDRHProductJurisdiction@fda.hhs.gov.

Section 510(m) of the FD&C Act provides that FDA may exempt a class II device from the premarket notification requirements under section 510(k) of the FD&C Act, if FDA determines that premarket notification is not necessary to provide reasonable assurance of the safety and effectiveness of the device type. FDA has determined premarket notification is necessary to provide reasonable assurance of the safety and effectiveness of the device type and, therefore, the device is not exempt from the premarket notification requirements of the FD&C Act. Thus, persons who intend to market this device type must submit a premarket notification containing information on the device for open surgical explant of vascular prostheses they intend to market prior to marketing the device.

Please be advised that FDA's decision to grant this De Novo request does not mean that FDA has made a determination that your device complies with other requirements of the FD&C Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the FD&C 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 Management System Regulation (QMSR) (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 FD&C Act; 21 CFR 1000-1050).

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System Rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its

label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

A notice announcing this classification order will be published in the Federal Register. A copy of this order and supporting documentation are on file in the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD 20852 and are available for inspection between 9 a.m. and 4 p.m., Monday through Friday.

As a result of this order, you may immediately market your device as described in the De Novo request, subject to the general control provisions of the FD&C Act and the special controls identified in this order.

For comprehensive regulatory information about medical devices and radiation-emitting products, 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).

If you have any questions concerning the contents of the letter, please contact Gordon Bryson at 301-837-7566.

Sincerely,

RACHEL E. NEUBRANDER -S

Rachel Neubrander, PhD
Director
DHT2B: Division of Circulatory Support,
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