December 11, 2020

PECA Labs
Doug Bernstein
Chief Executive Officer
4424 Penn Ave, Suite 201
Pittsburgh, Pennsylvania 15224

Re: K202471
Trade/Device Name: exGraft ePTFE Vascular Graft, exGraft Carbon ePTFE Vascular Graft
Regulation Number: 21 CFR 870.3450
Regulation Name: Vascular Graft Prosthesis
Regulatory Class: Class II
Product Code: DSY
Dated: August 26, 2020
Received: August 28, 2020

Dear Doug Bernstein:

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,

for Carmen Gacchina Johnson, PhD
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)*
K202471

Device Name
exGraft ePTFE Vascular Graft, exGraft Carbon ePTFE Vascular Graft

Indications for Use *(Describe)*
The exGraft and exGraft Carbon ePTFE Vascular Grafts are indicated for use as vascular prostheses.

exGraft and exGraft Carbon ePTFE Vascular Grafts are intended for use as vascular prostheses for replacement or bypass of diseased vessels in patients suffering occlusive or aneurysmal diseases, in trauma patients requiring vascular replacement, for dialysis access, or for other vascular procedures.

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:

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PECA labs

K202471

# 510(k) Summary

(as required by 21 CFR 807.92)

## I. SUBMITTER

PECA Labs, Inc.
4424 Penn Avenue
Suite 201
Pittsburgh, PA 15224
Phone: (412) 482-3755
Establishment Registration Number: 3013718163

Contact Person: Doug Bernstein, Chief Executive Officer
Date Prepared: December 11, 2020

## II. DEVICE

| | |
|---|---|
| Name of Device: | exGraft ePTFE Vascular Graft, exGraft Carbon ePTFE Vascular Graft |
| Common or Usual Name: | Vascular Graft |
| Classification Name: | 21 CFR 870.3450 Prosthesis, Vascular Graft |
| Regulatory Class: | Class II |
| Product Code: | DSY |

## III. PREDICATE DEVICE

Gore-Tex Vascular Grafts and Gore-Tex Stretch Vascular Grafts [K013250].

exGraft and exGraft Carbon ePTFE Vascular Grafts [K183613] are used as reference device.

The predicate and reference devices have not been subject to a design-related recall.

## IV. DEVICE DESCRIPTION

The exGraft and exGraft Carbon ePTFE Vascular Grafts are single use sterile vascular grafts constructed of expanded polytetrafluoroethylene (ePTFE) with a radiopaque ink applied to the surface. The exGraft Carbon ePTFE vascular grafts also contain a carbon coating impregnated into the inner surface of the graft wall.

## V. INDICATIONS FOR USE

The exGraft and exGraft Carbon ePTFE Vascular Grafts are indicated for use as vascular prostheses.

exGraft and exGraft Carbon ePTFE Vascular Grafts are intended for use as vascular prostheses for replacement or bypass of diseased vessels in patients suffering occlusive or aneurysmal diseases, in trauma patients requiring vascular replacement, for dialysis access, or for other vascular procedures.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

**Compared to the predicate device Gore-Tex Vascular Grafts and Gore-Tex Stretch Vascular Grafts [K013250]:**

The proposed exGraft and exGraft Carbon ePTFE Vascular Grafts and the predicate device have the following similarities:

- Same intended use
- Same basic design and material
- Same basic configurations
- Same basic packaging configuration

The proposed exGraft and exGraft Carbon ePTFE Vascular Grafts and the predicate device have the following differences:

- Addition of radiopaque ink pad printed on the outer (abluminal) surface of the exGraft and exGraft Carbon ePTFE Vascular Grafts
- No additional outer ePTFE wrap/coating on the abluminal surface of the exGraft and exGraft Carbon ePTFE Vascular Grafts
- Addition of carbon impregnation on the inner (luminal) surface of the exGraft Carbon ePTFE Vascular Grafts.

The differences stated above are considered technological differences. However, there are no new questions of safety and effectiveness raised by these differences.

VII. PERFORMANCE DATA

The proposed exGraft and exGraft Carbon ePTFE Vascular Grafts leverage historical data from the reference device, the exGraft and exGraft Carbon ePTFE Vascular Grafts, cleared under K183613.

In addition, the following testing was conducted to support substantial equivalence:

- Probe Burst Strength
- Longitudinal Tensile Strength
- Circumferential Tensile Strength
- Kink Radius
- Microscopic Porosity
- Suture Retention Strength
- Strength After Repeated Puncture

- Water Entry Pressure
- Conduit Dimensioning (including Relaxed Internal Diameter, Wall Thickness, and Length)

CONCLUSION

Compared to the predicate device, the exGraft and exGraft Carbon ePTFE Vascular Grafts has the same intended use and the technological differences do not raise different questions of safety and effectiveness. Based on historical data and performance testing, the exGraft and exGraft Carbon ePTFE Vascular Grafts are substantially equivalent to the predicate device.