January 17, 2024

PECA Labs, Inc.
Doug Bernstein
Chief Executive Officer
4424 Penn Ave., Ste 201
Pittsburgh, Pennsylvania 15224

Re: K233783
Trade/Device Name: exGraft ePTFE Vascular Grafts, exGraft Carbon ePTFE Vascular Grafts
Regulation Number: 21 CFR 870.3450
Regulation Name: Vascular Graft Prosthesis
Regulatory Class: Class II
Product Code: DSY, DYF
Dated: November 24, 2023
Received: November 27, 2023

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 (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,

Rohini Retarekar -S

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K233783

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.

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PECA labs

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: 16 January 2024

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, of 6mm and Greater Diameter 21 CFR 870.3450 Prosthesis, Vascular Graft, of less than 6mm Diameter
Regulatory Class:	Class II
Product Code:	DSY, DYF

III. PREDICATE DEVICE

exGraft and exGraft Carbon ePTFE Vascular Grafts [K221628]

Impra Carboflo ePTFE Vascular Grafts [K004012 and K004011], Impra ePTFE Vascular Grafts [K954582 and K830543], are used as reference devices.

The predicates and references 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 exGraft and exGraft Carbon ePTFE Vascular Grafts [K221628]:

The proposed exGraft and exGraft Carbon have the following similarities:

- Same design and material
- Same sterilization processes and method
- Same packaging materials, processes, design and location
- Available in Carbon and Non-Carbon configurations
- Same radiopaque ink on the outer (abluminal) surface

The proposed exGraft and exGraft Carbon have the following differences:

- Change in conduit manufacturing supplier for Non-Carbon configurations
- Change in the wall thickness of some configurations for Non-Carbon configurations
- Reduction of blue lines on the graft from two to one for Non-Carbon configurations

VII. PERFORMANCE DATA

There have been no changes to the exGraft Carbon ePTFE Vascular Grafts and thus those configurations utilize the same performance data as the exGraft and exGraft Carbon ePTFE Vascular Grafts cleared under K221628.

For the exGraft ePTFE Vascular Grafts (Non-Carbon) additional performance data been included within the submission and its appendices, including

- Burst Strength
- Strength after Repeated Puncture
- Tensile Strength
- Suture Retention Strength
- Kink Radius
- Water Entry Pressure
- Microscopic Porosity
- Wall Thickness Eccentricity

- Wall Thickness

CONCLUSION

The exGraft and exGraft Carbon ePTFE Vascular Grafts are substantially equivalent to the predicate devices exGraft and exGraft Carbon ePTFE Vascular Graft cleared under K221628.