August 21, 2018

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

Re: K180957
Trade/Device Name: exGraft and exGraft Carbon ePTFE Vascular Grafts
Regulation Number: 21 CFR 870.3450
Regulation Name: Vascular Graft Prosthesis
Regulatory Class: Class II
Product Code: DSY
Dated: July 13, 2018
Received: July 16, 2018

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Brian D. Pullin -S

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
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)*
K180957

Device Name
exGraft and exGraft Carbon ePTFE Vascular Grafts

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

The exGraft and exGraft Carbon ePTFE Vascular Grafts are intended for use as subcutaneous arteriovenous conduits for blood access, bypass, or reconstruction of peripheral arterial blood vessels.

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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PECAlabs

K180957

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

Contact Person: Doug Bernstein, Chief Executive Officer
Date Prepared: August 16, 2018

II. DEVICE

Name of Device:	exGraft and exGraft Carbon ePTFE Vascular Grafts
Common or Usual Name:	Vascular Graft
Classification Name:	21 CFR 870.3450 Prosthesis, Vascular Graft, of 6 mm and Greater Diameter
Regulatory Class:	Class II
Product Code:	DSY

III. PREDICATE DEVICE

Impra Carboflo ePTFE Vascular Grafts, K004011 and Impra ePTFE Vascular Grafts, K954582

The predicates 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 outer 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.

The exGraft and exGraft Carbon ePTFE Vascular Grafts are intended for use as subcutaneous arteriovenous conduits for blood access, bypass, or reconstruction of peripheral arterial blood vessels.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The proposed exGraft and exGraft Carbon and the predicate devices Impra Carboflo and Impra ePTFE vascular graft have the following similarities:

- Same basic design and material
- Sterilized using the same material and processes
- Same packaging material and construction
- Carbon impregnated and non-carbon impregnated

The proposed exGraft and exGraft Carbon and the predicate devices Impra Carboflo and Impra ePTFE vascular graft have the following differences:

- exGrafts include radiopaque ink applied to the outer surface

The radiopaque ink is considered a technological difference. However, there are no new questions of safety and effectiveness raised by the addition of the ink.

VII. PERFORMANCE DATA

Biocompatibility and bench testing were performed to demonstrate substantial equivalence to the predicate device.

Biocompatibility Evaluation

The biocompatibility evaluation for the exGraft and exGraft Carbon was conducted in accordance with FDA Guidance "Use of International Standard ISO 10993-1, "Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing Within a Risk Management Process" issued on June 16, 2016 and International Standard ISO 10993-1:2009 "Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing Within a Risk Management Process," as recognized by FDA. The battery of testing included the following tests:

- Cytotoxicity
- Sensitization
- Irritation or Intracutaneous Reactivity
- Acute Systemic Toxicity
- Material-Mediated Pyrogen Testing
- Implantation
- Hemocompatibility

Chemical characterization and toxicological risk assessment were used to address the following endpoints:

- Subacute/Subchronic Systemic Toxicity
- Chronic Systemic Toxicity
- Genotoxicity
- Carcinogenicity

The exGraft and exGraft Carbon are single use devices and are considered blood contact implant devices with a contact duration of permanent (greater than 30 days).

Bench Testing

Bench testing of the exGraft and exGraft Carbon included the following tests:

- Probe Burst Strength
- Suture Retention Strength
- Longitudinal Tensile Strength
- Circumferential Tensile Strength
- Water Entry Pressure
- Microscopic Porosity (Upper and Lower Limit)
- Strength After Repeated Puncture
- Kink Radius
- Ink Thickness
- Accelerated Ink Wear
- MRI Safety Evaluation

CONCLUSION

The exGraft and exGraft Carbon ePTFE Vascular Grafts are substantially equivalent to the currently marketed Impra Carboflo ePTFE Vascular Graft (K004011) and Impra ePTFE Vascular Graft (K954582).