May 7, 2021

RENU Medical, Inc
Darren DeMerritt
Director RA/QA
830 80th ST SW
Suite 100
Everett, Washington 98203

Re: K203847
Trade/Device Name: Reprocessed Tri Pulse Compression Garment
Regulation Number: 21 CFR 870.5800
Regulation Name: Compressible limb sleeve
Regulatory Class: Class II
Product Code: JOW
Dated: April 8, 2021
Received: April 9, 2021

Dear Darren DeMerritt:

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 Nicole Gillette
Assistant Director (Acting)
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

The item numbers included in the scope of this 510(k) submission are as follows:

Item No	Sleeve Description
RM-TRP10	Flowtron Regular Sequential Calf Garment
RM-TRP20	Flowtron Large Sequential Calf Garment
RM-TRP30	Flowtron Regular Sequential Thigh Garment
RM-TRP40	Flowtron Large Sequential Thigh Garment
RM-TRP60L	Flowtron Bariatric Sequential Calf Garment

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)*

K203847

Device Name
Reprocessed Tri Pulse Compression Garments

Indications for Use *(Describe)*

The RENU Medical Reprocessed Tri Pulse Compression Garment are to be used as a non-invasive therapeutic method to help prevent Deep Vein Thrombosis (DVT) and resulting pulmonary embolism.

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.

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510(k) Summary

Reprocessed Tri Pulse Compression Garments

Name & Address: RENU Medical, Inc.
830 80th ST SW Suite 100
Everett, WA 98203

Telephone: 425-353-1110

Fax: 425-353-9116

Prepared: December 29, 2020

Contact: Darren DeMerritt, Director RA/QA

Device Name: Reprocessed Tri Pulse Compression Garment

Common Name: Compressible Limb Sleeve

Classification

Class	Product Code	Classification Regulation
II	JOW	21 CFR 870.5800

Classification Name: Sleeve, Limb, Compressible

Predicate Devices: RENU Medical Reprocessed Compressible Limb Sleeves, cleared November 12, 2003 (K031559).

The following is a reference device:
Tri Pulse Garments cleared February 28, 2014, originally manufactured by Arjo Huntleigh (K133119).

Indications for Use: The RENU Medical Reprocessed Tri Pulse Compression Garment are to be used as a non-invasive therapeutic method to help prevent Deep Vein Thrombosis (DVT) and resulting pulmonary embolism.

Description: The Reprocessed Tri Pulse Compression Garment is a compression garment that is attached to a patient's limb. It is designed to work with the Arjo Flowtron ACS800 Pump and Arjo Flowtron ACS900 Pump only. Each garment is compressed alternately, applying pressure to the patient's limb, to help prevent deep vein thrombosis.

Models:

Model ID:	Device	Features
TRP10, TRP20, TRP30, TRP40 and TRP60	Tri Pulse Compression Garment	Sequential inflation providing active compression.

Substantial Equivalence:

The equivalence of the Tri Pulse garments is demonstrated using bench testing to determine that the reprocessing methods do not adversely affect the device from performing to the specifications outlined by the OEM predicate device (K133119).

The bench tested done on the devices was Cycle Verification Testing. This test examines the effect of the ReNu reprocessing system on the durability and functionality of the devices. The purpose of this test is to ensure that the Tri-Pulse Compression Garments can withstand the thermal temperatures that they're subject to during a reprocessing hot water pasteurization cycle.

During this test, a sample of devices were reprocessed 10 times each and subject to functional testing after each individual cycle in order to ensure that each device meets its functional requirements.

Each device was subject to a pasteurization cycle, then placed around PVC to simulate a patient use. Once situated, it was pumped up by an OEM pump and pressure readings were taken to ensure that the compression garment met its pressure and inflation time requirements and repeated until the Reprocessed Compression Garment met its cycle limit. This verification report, document ID #12915, titled, Cycle Verification Report, TRP DVT, can be found in section 18.4, Supporting Documents.

Additionally, the Reprocessed Tri Pulse Garments are substantially equivalent to other reprocessed compression garments and therefore are able to achieve the same cycle limits of other previously cleared reprocessed compression garments (K031559).

Technologies Summary:

Tri Pulse garments are constructed with a three-chamber bladder enclosed in a polyester garment, which is wrapped around the limb and secured with hook and eye tabs. When connected to the pump,

	the garment inflates through a single connecting tube to generate a sequential compression effect on the limb. Reprocessing the Tri-Pulse Compression Garment is conducted by achieving high-level disinfection via thermal disinfection methods. This process is conducted by holding the devices at or above a predetermined specified temperature for a predetermined specified duration.
Conclusion:	The data detailed within submission demonstrates that the device is as safe and effective as the predicate and performs as well as the legally marketed predicate devices, identified in this summary.