December 23, 2024

ElastiMed Ltd.
% John J. Smith
Partner
Hogan Lovells US LLP
Columbia Square
555 13th Street, NW
Washington, District of Columbia 20004

Re: K243177
Trade/Device Name: SACS PRO
Regulation Number: 21 CFR 890.5650
Regulation Name: Powered Inflatable Tube Massager
Regulatory Class: Class II
Product Code: IRP
Dated: September 30, 2024
Received: September 30, 2024

Dear John J. Smith:

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.

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.

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,

Heather L. Dean -S

Heather Dean, PhD
Assistant Director, Acute Injury Device Team
DHT5B: Division of Neuromodulation and
Physical Medicine Devices
OHT5: Office of Neurological and
Physical Medicine Devices
Office of Product Evaluation and Quality
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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)*
K243177

Device Name
SACS PRO

Indications for Use *(Describe)*
The ElastiMed's SACS PRO device is a portable and lightweight device intended to provide compression in both sustained and intermittent settings and by doing so, aids in the stimulation of blood flow in the legs.

The SACS PRO device is intended to temporarily relieve minor muscle aches and/or pains, and to temporarily increase circulation to the treated areas. The device can be used in Clinics, hospital, athlete training, and home environments.

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.

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510(k) SUMMARY

ElastiMed's SACS PRO Device

Submitter

ElastiMed Ltd.

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Date Prepared: December 10, 2024

Name of Device: SACS PRO

Common or Usual Name: Compression Device

Classification Name: Powered inflatable tube massager

Regulatory Class: II

Product Code: IRP

C.F.R. Section no.: 21 C.F.R. § 890.5650

Predicate Devices:

- Primary Predicate: NormaTec Industries, LP, Normatec Go (K221666)
- Secondary Predicate: ElastiMed Ltd., SACS , (K232300)

Device Description

The ElastiMed SACS PRO is a lightweight, portable, rechargeable battery powered device, aiding in the stimulation of blood flow in the lower limb through sequential compression.

The SACS PRO device imbeds three Electro Active Polymer (EAP) straps, that sequentially stretch and contract when stimulated by an electric charge. The timely sequential upward contractions of the straps compress the limb, allowing for the repetitive squeezing and relieving actions that mimic normal muscle contractions. The device is supplied with a rechargeable battery which is incased in the fabric casing, and a microprocessor which is imbedded within the control box, located at the front of the unit. The one touch operation control box also imbeds a buzzer, LED light indicator, micro speaker, and a micro-USB port (for charging). The device can be used in Clinics, hospital, athlete training, and home environments.

Intended Use / Indications for Use

The ElastiMed's SACS PRO device is a portable and lightweight device intended to provide compression in both sustained and intermittent settings and by doing so, aids in the stimulation of blood flow in the legs.

The SACS PRO device is intended to temporarily relieve minor muscle aches and/or pains, and to temporarily increase circulation to the treated areas. The device can be used in Clinics, hospital, athlete training, and home environments.

Summary of Technological Characteristics

The SACS PRO device is substantially equivalent to both listed predicate devices in that all devices use a microprocessor to provide intermittent compression to simulate muscle contractions in the lower limbs aiding the return of venous flow.

Like the predicate devices, the SACS PRO device is lightweight, portable, and wraps around the lower limb. Identical to the secondary predicate device, the SACS PRO may be used on one or both legs. When used on both legs, the wraps operate separately.

The predicates and subject devices all have the same intended use; specifically, the subject and the primary predicate (Normatec Go) have identical Over-the-Counter (OTC) indications for use. Both the subject device and the secondary predicate device have three discrete compression zones with similar on-body pressure and cycle times (2-3 seconds of compression, with approximately 24 seconds of rest period before the cycle repeats, i.e., 2 cycles per minute), providing sequential compression, which cannot be changed. In all devices, compression is controlled by a microprocessor-controlled system having a user interface, which in addition to controlling the system, provides battery and system information (including error notification). All compression systems are encased in soft, non-latex fabrics for patient comfort. The SACS PRO, like the secondary predicate device, is supplied with a rechargeable battery, which can be charged when not in use.

The subject device and the secondary predicate device (SACS) are entirely identical in design and physical form. The sole difference between the subject device and the secondary predicate device is the fact that the secondary predicate device is for prescription use only while the subject device (like the primary predicate device) may be supplied as an OTC device. All systems are provided non-sterile and are intended for single patient use.

Comparison of Technological Characteristics

	ElastiMed SACS PRO **(Subject Device)**	**Normatec Go** **K221666** **(Primary Predicate Device)**	**ElastiMed SACS** **K232300** **(Secondary Predicate Device)**
Intended Use and Indications for Use	The ElastiMed's SACS PRO device is a portable and lightweight device intended to provide compression in both sustained and intermittent settings and by doing so, aids in the stimulation of blood flow in the legs. The SACS PRO device is intended to temporarily relieve minor muscle aches and/or pains, and to temporarily increase circulation to the treated areas. The device can be used in Clinics, hospital, athlete training, and home environments.	*The Normatec Go is an air pressure massager intended to temporarily relieve minor muscle aches and/or pains, and to temporarily increase circulation to the treated areas.*	The ElastiMed's SACS device is a portable and lightweight device intended to provide compression in both sustained and intermittent settings by stimulating blood flow in the legs. The SACS device is intended for: - Aid in the prevention of DVT. - Enhance blood circulation. - Diminish post-operative pain and swelling. - Reduce wound healing time. - Aid in the treatment and healing of stasis dermatitis, venous stasis ulcers, arterial and diabetic leg ulcers, chronic venous insufficiency, chronic lymphedema, and reduction of edema in the lower limbs. - As a prophylaxis for DVT by persons expecting to be stationary for long periods of time. - Reduction of edema associated with soft tissue injuries, such as burns, postoperative or post-immobilization edema, or ligament sprains. The device can be used in the home or clinical setting.
Intended Use Environment	Clinics, hospital, athlete training, and home environments.	Clinics, hospital, athlete training, and home environments	Home or clinical setting
Technological Characteristics	Portable device that wraps around the lower limb and can be used on one or both legs	Portable device that wraps around the lower limb and can be used on one or both legs	Portable device that wraps around the lower limb and can be used on one or both legs

	ElastiMed SACS PRO (Subject Device)	Normatec Go K221666 (Primary Predicate Device)	ElastiMed SACS K232300 (Secondary Predicate Device)
Main components	Three compression / relaxation enabling straps cased within a fabric casing	Control unit mounted to inflatable segment with compressor and valve system that sequentially inflates cells	Three compression / relaxation enabling straps cased within a fabric casing
Weight	lightweight (<1kg)	1.2 lbs	lightweight (<1kg)
Power Source	3 AA 1.2V NiMH rechargeable batteries	Integrated rechargeable battery	3 AA 1.2V NiMH rechargeable batteries
Safety Features	LED / Buzzer indicators for battery status and general user interface indications	LED / Buzzer indicators for battery status and general user interface indications	LED / Buzzer indicators for battery status and general user interface indications
Software	Validated per applicable standards and guidance documents	Validated per applicable standards and guidance documents	Validated per applicable standards and guidance documents
Sterility	Provided non-sterile	Provided non-sterile	Provided non-sterile
Opening and closing mechanism	Hooks and Loops (Velcro)	Hooks and Loops (Velcro)	Hooks and Loops (Velcro)
Operation Mode	Sustained and intermittent	Sequential Gradient, Peristaltic and Pulsing	Sustained and intermittent
Pressure	Up to 40mmHg	40 mmHg to 220 mmHg	Up to 40mmHg
Cycle Duration	30 seconds	Stays on until the user turns it off or can be set up to turn off in a range of 15 minutes to 60 minutes	30 seconds

Performance Data

Non-clinical validation, including electrical safety, EMC, software validation, environmental / shipping, life cycle (durability and shelf-life), and performance testing verifying performance attributes, pressure delivery, geometrical attributes, and system durability, have shown that the SACS PRO device has performance characteristics consistent with the predefined requirements for the devices' intended and indications for use. Since the subject device and the secondary predicate device share identical specifications, i.e., identical device master records, all performance data as provided for the approval of the secondary predicate device are applicable for the subject device.

The following table summarizes the evaluations conducted:

Testing	Summary
Electrical Safety and EMC	EMC was tested according to ANSI AAMI IEC 60601-1-2:2014 [Including AMD 1:2021]. Electrical Safety was tested according to ANSI AAMI ES60601-1:2005/(R)2012 & A1:2012, C1:2009/(R)2012 & A2:2010/(R)2012 (Cons. Text) [Incl. AMD2:2021]. All pass/fail criteria were based on the device's functions, indications, intended use, and essential performance.
Software Validation	Software validation was conducted per FDA's Content of Premarket Submissions for Device Software Functions (June 14, 2023) and ANSI AAMI IEC 62304:2006/A1:2016 [Including Amendment 1 (2016)].
Packaging Design Qualification (Distribution Cycle Simulation)	Device safety and performance was validated after simulated distribution cycle conditioning and 6-month accelerated aging.
Mechanical Evaluation	Pristine and aged devices were tested to withstand mechanical force both per specification during simulated use and far exceeding requirement specifications (extreme stress testing).
Functional Evaluation	System-level verification testing of device performance with usability validation was conducted.
Device Durability	System-level functional testing after expected use life conditioning was conducted to validate device durability.

Conclusions

The ElastiMed SACS PRO device has the same intended and indications for use as the primary predicate device. The results of non-clinical testing (conducted for the identical secondary predicate device) demonstrates that the device met all performance requirements. Therefore, the subject device is substantially equivalent to the predicate devices.