December 22, 2023

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

Re: K232300
Trade/Device Name: SACS
Regulation Number: 21 CFR 870.5800
Regulation Name: Compressible Limb Sleeve
Regulatory Class: Class II
Product Code: JOW
Dated: November 17, 2023
Received: November 17, 2023

Dear John 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.

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,

Nicole M. Gillette -S

Nicole Gillette
Assistant Director
DHT2B: Division of Circulatory Support,
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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)*

K232300

Device Name

SACS

Indications for Use *(Describe)*

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.

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

ElastiMed's SACS Device

K232300

Submitter

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Date Prepared: November 17, 2023

Name of Device: SACS

Common or Usual Name: Compression Device

Classification Name: Sleeve, Limb, Compressible

Regulatory Class: II

Product Code: JOW

C.F.R. Section no.: 21 C.F.R. § 870.5800

Predicate Device:

Recovery Force LLC., RF1400 Active Compression Wrap (K162481)

Reference Device:

Tactile Systems Technology Inc., ActiTouch ACT-Adaptive Compression Therapy System (K131193)

Device Description

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

The SACS 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 the home or clinical setting.

Intended Use / Indications for Use

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.

Summary of Technological Characteristics

The SACS device is equivalent to the 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 device is light-weight, portable, and wraps around the lower limb. Similar to the predicate device, the SACS 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 and similar indications for use and contraindications. Although the subject device uses a different technology to enable compression (electrical stimulation allowing strap relaxation thus pressure relief; rather than using nitinol phase transition / air delivery through tubing which is used in the predicate devices), the subject device has similar performance characteristics to the predicates in terms of cycle time and applied / on-body pressure. Both the subject device and the predicate devices 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.

All systems are prescription only, provided non-sterile, and are intended for single patient use. The SACS, like the predicate device is supplied with a rechargeable battery, which can be charged when not in use.

Performance Data

Nonclinical validation including electrical safety, EMC, software validation, environmental / shipping, life cycle (durability and shelf-life), and performance testing, verified performance attributes, pressure delivery, geometrical attributes and system durability have shown that the SACS device has performance characteristics consistent with the predefined requirements for the devices' intended and indications for use.

Conclusions

The ElastiMed SACS device has the same intended use, similar indications for use and performance characteristics as the predicate devices. The results of non-clinical testing demonstrates that the device met all performance requirements. Therefore, the subject device is substantially equivalent to the predicate devices