July 31, 2026

Tactile Medical
% Mark Spreeman
Regulatory, Quality, and Compliance Consultant
Duval & Associates, P.A.
Medical Arts Bldg.
825 Nicollet Mall, Suite 1820
Minneapolis, Minnesota 55402

Re: K253555
Trade/Device Name: Flexitouch® Plus Advanced Pneumatic Compression System
Regulation Number: 21 CFR 870.5800
Regulation Name: Compressible Limb Sleeve
Regulatory Class: Class II
Product Code: JOW, PPS
Dated: July 8, 2026
Received: July 8, 2026

Dear Mark Spreeman:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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,

NICOLE M. GILLETTE -S

Nicole Gillette
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)*
K253555

Device Name
Flexitouch Plus Advanced Pneumatic Compression System

Indications for Use *(Describe)*
The Flexitouch Plus system and garments for legs, arms, trunk and chest are intended for use by medical professionals and patients who are under medical supervision to increase lymphatic flow in the treatment of many conditions, such as:

- Lymphedema
- Primary lymphedema
- Post-mastectomy edema
- Edema following trauma and sports injuries
- Post-immobilization edema
- Venous insufficiency
- Reduction in wound healing time
- Treatment and assistance in healing stasis dermatitis, venous stasis ulcers, or arterial ulcers and diabetic leg ulcers
- Lipedema
- Phlebolymphedema

The Flexitouch Plus system and garments for the head and neck are intended for use by medical professionals and patients who are under medical supervision for the treatment of head and neck lymphedema.

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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510(k) Summary

510(k) Owner: Tactile Medical
3701 Wayzata Blvd
Suite 300
Minneapolis, MN 55416
Contact: Sunday Hoy
612.355.5121

Date prepared: November 14, 2025

Device Name:	Trade Name:	Flexitouch® Plus Advanced Pneumatic Compression System
	Common Names:	Sleeve, Limb, Compressible Sleeve, Head and Neck, Compressible
	Classification Name:	Compressible Limb Sleeve
	Regulation:	21 CFR §870.5800
	Regulatory Classification:	2
	Product Codes:	JOW PPS

Predicate Devices: **Primary:** Flexitouch® Plus Advanced Pneumatic Compression System (K203178)
Additional: Dayspring (K223228)

Device Description

The Flexitouch Plus system is an advanced pneumatic compression device to stimulate the lymphatic system. The device helps direct and move excess fluid from an impaired lymphatic region to healthy regions, where fluid can be absorbed and processed naturally by your body.

The system employes a controller unit, which is a programmable pneumatic compressor with four connector outlets. Each connector has eight outflow ports to plug in garment hoses. Air passes through the hoses, delivering treatment through the sequential inflation and deflation of up to 32 air chambers in the garments. By selecting the appropriate treatment program, calibrated gradient pressure is delivered to the chambers and assists in moving excess fluid out of the affected areas.

Data is transmitted from the Flexitouch Plus device to the Kylee mobile application using Bluetooth technology. The mobile application enables viewing usage and session data, recording symptoms, and displaying information into an Activity Report that can be shared with a healthcare provider. Kylee also enables firmware updates to the Controller through over-the-air (OTA) functionality.

Indications for Use
The Flexitouch Plus system and garments for legs, arms, trunk and chest are intended for use by medical professionals and patients who are under medical supervision to increase lymphatic flow in the treatment of many conditions, such as:

- Lymphedema
- Primary lymphedema
- Post-mastectomy edema
- Edema following trauma and sports injuries
- Post-immobilization edema
- Venous insufficiency
- Reduction in wound healing time
- Treatment and assistance in healing stasis dermatitis, venous stasis ulcers, or arterial ulcers and diabetic leg ulcers
- Lipedema
- Phlebolymphedema

The Flexitouch Plus system and garments for the head and neck are intended for use by medical professionals and patients who are under medical supervision for the treatment of head and neck lymphedema.

Comparison of Technological Characteristics with the Predicate Devices
The Flexitouch Plus system has the same Intended Use as the predicate devices with the same Indications for Use as the primary predicate device.

The Flexitouch Plus system also employs the same technological characteristics of either the primary predicate and/or the secondary predicate devices.

Performance Data
Connectivity technology and the minor modifications implemented were successfully qualified and demonstrated the safety and performance of the Flexitouch Plus system:

- Software Verification
- Cybersecurity Testing
- EMC Testing
- Accelerated Life Testing
- Usability Testing
- Design Verification & Validation Testing
- Distribution and Environmental Testing

Conclusion
Inclusive of the information provided in this submission, the Flexitouch Plus system has demonstrated that it is as safe, as effective, and performs as well as the predicate devices.

As set out in section 513(i) of the FD&C Act, a determination of substantial equivalence requires: 1) the same intended use, and 2) either the same technological characteristics or differences in technological characteristics that do not raise different questions of safety or effectiveness. Both of these conditions have been met and support a determination of substantial equivalence.