December 20, 2020

Tactile Systems Technology, Inc. (DBA Tactile Medical)
℅ Lauren Barnes
Regulatory Consultant
The Tamarack Group - MPLS, LLC
2584 Upton Avenue South
Minneapolis, Minnesota 55405

Re: K203178
Trade/Device Name: Flexitouch Plus System (PD32-G3)
Regulation Number: 21 CFR 870.5800
Regulation Name: Compressible Limb Sleeve
Regulatory Class: Class II
Product Code: JOW, PPS
Dated: October 22, 2020
Received: October 26, 2020

Dear Lauren Barnes:

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 Fernando Aguel
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: 0MB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

K203178

Device Name
Flexitouch Plus System (PD32-G3)

Indications for Use *(Describe)*

The Flexitouch Plus Systems 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
- Reducing wound healing time
- Treatment and assistance in healing stasis dermatitis, venous stasis ulcers, or arterial and diabetic leg ulcers
- Lipedema
- Phlebolymphedema

The Flexitouch 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)*

IXI 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 for the Flexitouch Plus System (PD32-G3)

Prepared December 16, 2020

Submitter

Manufacturer:

Tactile Systems Technology, Inc.
(DBA Tactile Medical)
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612-355-5100

Contact Person:

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General Information

Device Name:	Flexitouch Plus System PD32-G3
Common / Usual Name:	Compressive limb sleeve system
Classification Name:	Sleeve, Limb, Compressible (21 CFR 870.5800) Sleeve, Head, and Neck, Compressible (21 CFR 870.5800)
Product Codes:	JOW, PPS
Device Class:	Class 2
Primary Predicate Device:	Flexitouch System PD32-G3 (K170216)
Secondary Predicate Device:	Lympha Press Optimal Plus System (K182003)

Device Description

The Flexitouch Plus System is an advanced pneumatic compression device clinically proven 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. Flexitouch Plus garment chambers inflate sequentially with each chamber inflating before the adjacent distal chamber fully deflates. This creates a dynamic wave of therapy that directs fluid into the lymphatic capillaries while maintaining distal pressure to prevent distal backflow.

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 issues
-Post immobilization edema
-Venous insufficiency
-Reducing wound healing time
-Treatment and assistance in healing stasis dermatitis, venous stasis ulcers, 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 supervision for the treatment of head and neck lymphedema.

Intended Use

The intended use and contraindications for the subject and predicate devices are provided and compared in the table below. Compared to the primary predicate device, the contraindication for cancer is removed from the subject device labeling.

Removal of the cancer contraindication does not suggest a new disease, condition or patient population compared to the intended use of the secondary predicate device. Considering the current position of the International Society of Lymphology regarding this potential concern for cancer patients, and the fact that FDA has cleared the secondary predicate device with no cancer contraindication, the Flexitouch Plus System without the cancer contraindication poses no increased or different risk compared to the predicate devices, nor does this type of labeling change affect the indications for use in a way that could significantly affect the safety or effectiveness of the device and the intended users.

	Subject Device(s)	**Primary Predicate(s)**	**Secondary Predicate**	**Comparison**
Identification	Flexitouch Plus System PD32-G3 (Rx) 510(k): K203178	Flexitouch System PD32-G3 (Rx) 510(k): K170216	Lympha Press Optimal Plus (Rx) 510(k): K182003	Similar
Intended 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	The Flexitouch system and garments for legs, arms, trunk, and chest are intended for use by medical professionals and patients who are under medical supervision, for the treatment of many conditions such as: -Lymphedema -Primary lymphedema -Post mastectomy edema	The device is intended for use by medical professionals, and patients who are under medical supervision in treating many conditions such as: -Primary lymphedema -Secondary lymphedema -Venous insufficiency -Venous stasis ulcers -Dysfunction of the muscle pump	Compared to primary predicate, subject device adds clarifying language to the intended use, including indications for lipedema and phlebolymphedema and a phrase explaining that the device increases lymphatic flow to treat the conditions indicated.

	-Post mastectomy edema -Edema following trauma and sports issues -Post immobilization edema -Venous insufficiency -Reducing wound healing time -Treatment and assistance in healing stasis dermatitis, venous stasis ulcers, 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 supervision for the treatment of head and neck lymphedema.	-Edema following trauma and sports issues -Post immobilization edema -Venous insufficiency -Reducing wound healing time -Treatment and assistance in healing stasis dermatitis, venous stasis ulcers, arterial ulcers, and diabetic leg ulcers The Flexitouch system and garments for the head and neck are intended for use by medical professionals and patients who are under supervision for the treatment of head and neck lymphedema.	-Post mastectomy edema -Edema following trauma and sports issues -Post immobilization edema -Reducing wound healing time -Reduction of pain and swelling after injury and surgery -The device may also be beneficial in the management of Lipoedema. The device is intended for hospital, home, and clinic use.	
Contraindications	The Flexitouch Plus system should not be used if you have one or more of the following conditions: -Heart failure (acute pulmonary edema, decompensated acute heart failure) -Acute venous disease (acute thrombophlebitis, acute deep venous thrombosis, acute pulmonary embolism) -Severe peripheral artery disease (critical limb ischemia including ischemic rest pain, arterial wounds, or gangrene) -Active skin or limb infection/inflammatory disease (acute cellulitis, other uncontrolled skin, or	The Flexitouch system should not be used if you have one or more of the following conditions: -Heart failure (acute pulmonary edema, decompensated acute heart failure) -Acute venous disease (acute thrombophlebitis, acute deep venous thrombosis, acute pulmonary embolism) -Severe peripheral artery disease (critical limb ischemia including ischemic rest pain, arterial wounds, or gangrene) -Active skin or limb infection/inflammatory disease (acute cellulitis, other uncontrolled skin, or untreated	Use of Lympha Press is not recommended in the presence of one or more of the following conditions: -Known or suspected deep vein thrombosis (DVT) or pulmonary embolus -During the inflammatory phlebitis process -Acute infection of the affected limb -Decompensated cardiac failure -Severe arteriosclerosis or other ischemic vascular disease -Any circumstance where increased venous and lymphatic return is undesirable -Due to movement of fluids in the body when using the system, exercise caution when	Compared to the primary predicate, the subject device removes the contraindication for active cancer but otherwise has an identical list of contraindications. Neither the subject device nor the secondary predicate has a contraindication for patients with cancer.

	untreated inflammatory skin disease) -Any circumstance where increased lymphatic or venous return is undesirable The Flexitouch trunk accessory should not be used during pregnancy.	inflammatory skin disease) -Active cancer (cancer that is currently under treatment, but not yet in remission) -Any circumstance where increased lymphatic or venous return is undesirable The Flexitouch trunk accessory should not be used during pregnancy.	using on patients with heart disease. -High pressure is not recommended for patients who have peripheral occlusion disease. The abdominal area should not be treated during pregnancy.	

Technological Characteristics

There are no technology, engineering or performance differences between the subject device and the primary predicate device that require the submission of a new 510(k). They are the same in terms of control mechanisms, operating principle, energy type, sterilization, cleaning and disinfection, packaging, and expiration dating. No design changes made since the last Flexitouch 510(k) submission and clearance significantly affect use of the device. The manufacturer's risk assessment has not identified any new or significantly modified risks related to design changes. There have been no unexpected issues from verification and validation testing, nor has clinical data been necessary to support any design changes. Similarly, there are no materials differences between the subject device and the primary predicate device that require the submission of a new 510(k). The manufacturer's risk assessment has not identified any new or increased biocompatibility concerns related to materials changes since the last Flexitouch 510(k) submission and clearance. Thus, the subject device has no technological characteristics that raise different questions of safety or effectiveness compared to the predicate devices.

Safety and Performance Data

Safety and performance data submitted for the previously cleared Flexitouch system (primary predicate device) supports the subject device. No testing was necessary to support substantial equivalence for the Flexitouch Plus system with the cancer contraindication removed.

Substantial Equivalence Conclusion

The subject and primary predicate devices have the same intended use and apply similar technologies. They all automate manual lymphatic drainage and are used to reduce edema by compressing parts of the body to move lymphatic fluid. Compared to the primary predicate, there have been no changes to the materials, design, energy source or other features of the subject device that raise different questions of safety or effectiveness. Removing the contraindication for cancer agrees with secondary predicate device labeling and does not change the intended use compared to the predicate devices. Therefore, the subject device is substantially equivalent.