DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

May 26, 2017

Tactile Systems Technology, Inc. (dba Tactile Medical)
Thomas Dold
Vice President, Quality and Regulatory Affairs
1331 Tyler Street NE, Suite 200
Minneapolis, Minnesota 55413

Re: K170216
Trade/Device Name: Flexitouch® System, Model PD32-G3
Regulation Number: 21 CFR 870.5800
Regulation Name: Compressible Limb Sleeve
Regulatory Class: Class II
Product Code: JOW, PPS
Dated: April 21, 2017
Received: April 25, 2017

Dear Thomas Dold:

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. 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.

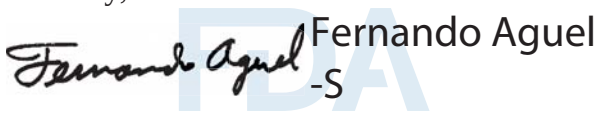
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,



for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K170216

Device Name
Flexitouch System, Model PD32-G3

Indications for Use *(Describe)*
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
- 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

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)*

☒ 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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Appendix A 510(k) Summary

Date Prepared: May 25, 2017

Submitter: Thomas Dold
Vice President, Quality and Regulatory Affairs
Tactile Systems Technology, Inc. (DBA Tactile Medical)
1331 Tyler Street NE, Suite 200
Minneapolis, Mn 55413
612-355-5100

Contact Person: Thomas Dold

Name of Device: Flexitouch® System PD32-G3

Classification: Sleeve, Limb, Compressible (21 CFR 870.5800)
Sleeve, Head, and Neck, Compressible (21 CFR 870.5800)

Product Code(s): JOW, PPS

Predicate Device: Tactile Systems Technology, Inc. Flexitouch® System (K153311)

Reference Device: Entré PD08-U (K143185)

Description of Device:

The Flexitouch ®system consists of two main components: a garment set and a pneumatic sequential controller. The garments are wrapped around affected region so that the garment fits snugly. The garments have multiple chambers that are filled with air to provide pneumatic compression therapy. Up to four (4) tubing harness assemblies containing eight (8) discrete individual air passage tubes connect individual garment chambers with the controller. Air passes through the tubes, delivering treatment via the sequential inflation and deflation of up to 32 air chambers in the garments.

Indications for Use:

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
- 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 medical supervision for the treatment of head and neck lymphedema.

Comparison to Technology Characteristics:

In addition to having the same indications for use, the Flexitouch® PD32-G3 has the same technology characteristics to the predicate devices with respect to design features, materials, and operating principal as demonstrated in the table below.

The key differences between this device and the predicate Flexitouch® System PD32-U, include the use of pressure sensing technology rather than time based pressure control and a full color LCD user interface.

Device Characteristic	**REFERENCE Tactile Systems Technology, Inc. Entré PD08-U (K143185)**	**PREDICATE Tactile Systems Technology, Inc. Flexitouch System® PD32-U (K153311)**	**Tactile Systems Technology, Inc. Flexitouch® System PD32-G3 (New Device K170216)**	**Difference**
Electrical Requirements	100 VAC-264 VAC ~ 50/60 Hz 14.4W	100-240 VAC, 1.0 A, 50/ 60 Hz	100–240 VAC 50/60 Hz	Same as PD32-U
Enclosure material	All plastic construction	All plastic construction	All plastic construction	Same
Manifold Assembly	Plastic construction with integrated air channel	Plastic construction with integrated air channel	Plastic construction with integrated air channel	Same
User Interface	Tactile Pushbuttons	Tactile Pushbuttons	Tactile Pushbuttons	Same
Software/ Hardware	Analog and digital electronic with microprocessor	Analog and digital electronic with microprocessor	Analog and digital electronic with microprocessor	Same
Chambers	8 Chambers	Up to 32 depending on garment size and types	Up to 32 depending on garment size and types	Same as PD32-U
Output	Sequential gradient pressure	Sequential calibrated gradient pressure	Sequential calibrated gradient pressure	Same as PD32-U
Garment Chamber Pressure Control	Pressure Based Control	Time Based Control	Pressure Based Control	Same as PD08-U

Summary of Tests

Comparative performance testing was used to verify the equivalence between the Flexitouch PD32-G3, which is the subject of this submission and the predicate devices. The test results verify that the device met all pre-specified performance criteria and is substantially equivalent to the predicate devices for its intended use. Clinical testing was not required to establish substantial equivalence with the predicate devices.

The following non-clinical performance testing was performed in support of the substantial equivalence determination.

- Electrical safety and performance testing were according to standard IEC 60601-1: 2005 and standard IEC 60601-1-2:2014.
- Software verification and validation testing were conducted and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices."
- Biocompatibility Testing – Cytotoxicity, Sensitization, Irritation per ISO 10993.
- Transportation Shipping Testing per ASTM D4169
- Device Storage Condition and Operational Condition Testing
- Pressure Verification Testing

Conclusion

The data included in this submission demonstrates that the Flexitouch® PD32-G3 is substantially equivalent to the legally marketed predicate device, Flexitouch® PD32-U (K153311).