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

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

Re: K153311
Trade/Device Name: Flexitouch System
Regulation Number: 21 CFR 870.5800
Regulation Name: Sleeve, Head and Neck, Compressible
Regulatory Class: Class II
Product Code: PPS, JOW
Dated: August 12, 2016
Received: August 15, 2016

Dear Mr. 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 yours,

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)*
K153311

Device Name
Flexitouch System

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 insufficiencies
- 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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K153311: 510(k) Summary

Submission Date: 16 November 2015

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

Contact person: Thomas A. Dold

Name of Device: Flexitouch® system

FDA Regulation: Sleeve, Head and Neck, Compressible (21 CFR 870.5800)

Device Classification: Class II

Predicate Device: Tactile Systems Technology, Inc. Flexitouch® system (K120972, K062818 & K013061)

Description of Device

The Flexitouch® system consists of two main components: a garment set and a pneumatic sequential controller. The garments are wrapped around an affected region so that the garment fits snugly. The garments have multiple chambers that are filled with air to provide for low-level compression therapy. Up to four (4) tubing harness assemblies containing eight (8) discrete individual air passage tubes connect individual garment chambers with the controller.

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 injuries
- Post immobilization edema
- Venous insufficiencies
- 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.

Comparison of Technological Characteristics:

The Flexitouch® system has the same technological characteristics to the predicate device with respect to, design, materials used, and construction. The head and neck garments referenced in this submission are indicated for use in head and neck lymphedema, a new anatomical location. The new garments use the same controller as the predicate device, with a separate program in the software specific for head and neck treatment. The table below summarizes the comparison of technological characteristics. Non-clinical and clinical testing results support use of the Flexitouch device in the new anatomical location, and demonstrate that no new questions of safety and effectiveness are raised.

	Flexitouch System including Head and Neck Garments (Current Submission K153311)	**Flexitouch System Predicate Device (K120972, K062818, K013061)**
Indications for Use	The Flexitouch® system and garments for legs, arms, trunk, and chest are indicated 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 insufficiencies, 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.	The Flexitouch® system is indicated 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 insufficiencies, reducing wound healing time, treatment and assistance in healing stasis dermatitis; venous stasis ulcers, or arterial and diabetic leg ulcers
FDA Classification	Class II	Class II
FDA Product Code	PPS (primary), JOW (secondary)	JOW
FDA Regulation	21 CFR 870.5800	21 CFR 870.5800
Prescription Required	Yes	Yes

Controller Design		
Size	5.5” x 12.25” x 10.5”	5.5” x 12.25” x 10.5”
Weight	8 lbs	8 lbs
Electrical Requirements	100-240 VAC, 1.0 A, 50/60 Hz UL/CUL	100-240 VAC, 1.0 A, 50/60 Hz UL/CUL
Enclosure Material	Plastic construction	Plastic construction
Manifold Assembly	Plastic construction with integrated air channels	Plastic construction with integrated air channels
User Interface	Tactile push buttons	Tactile push buttons
Software-concern Level	Moderate	Moderate
Software/Hardware	Analog and digital electronics with microprocessor	Analog and digital electronics with microprocessor
Chambers	Up to 32 depending on garment size and type	Up to 32 depending on garment size and type
Pressure Range	25-75 mmHg	25-75 mmHg
Inflation time per chamber	1-6 seconds	1-6 seconds
Output	Sequential/Intermittent	Sequential/Intermittent
Inflatable Garments		
Material	Nylon outer layer, polyurethane inner layer	Nylon outer layer, polyurethane inner layer
Port Material	Polyurethane	Polyurethane
Garment Connectors	Plastic construction	Plastic construction
Sterility	Non-sterile	Non-sterile
Garment Type and Sizes	Arm – left or right, short or long Chest – left or right, 4 sizes Trunk-thigh – left or right Universal Trunk Calf-foot – left or right, regular or EXT Trunk/thigh – left or right, short, long or EXT Full leg/trunk Full leg – left or right, short medium, long Head and Neck Garment	Arm – left or right, short or long Chest – left or right, 4 sizes Trunk-thigh – left or right Universal Trunk Calf-foot – left or right, regular or EXT Trunk/thigh – left or right, short, long or EXT Full leg/trunk Full leg – left or right, short medium, long

Summary of Performance Testing:

Comparative performance testing was completed to verify the equivalence between the Flexitouch® system with head and neck garments, which is the subject of this submission, and the predicate device. Testing included software verification and validation, garment inflation/deflation, and garment pressure withstand testing. The test results verify that the safety

and performance for the device met all pre-specified performance criteria and is substantially equivalent to the predicate device for its intended use.

Summary of Clinical Evaluation:

A prospective, single-arm, single-center study was conducted to evaluate ease of application, garment fit, garment comfort, and reduction in head/neck lymphedema in patients ≥ 18 years of age diagnosed with head and/or neck lymphedema without active cancer and at least 4 weeks post cancer treatment and/or radiation. Adverse events related to the device safety profile and facial and neck composite scores were monitored. The study confirmed that use of the device in the head and neck location does not cause harm and has the potential to perform as designed. A majority of subjects were able to don and doff the device by the second attempt, reported that the garment was very/somewhat comfortable, and experienced a decrease in facial composite score. The results indicate that the benefit-risk profile of the device for the indication for use in the head and neck is favorable.

Conclusion:

The results from the nonclinical and clinical device evaluations, which are referenced herein, demonstrate that the Flexitouch® system is substantially equivalent to the predicate device.