DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

May 7, 2015

Tactile Systems Technology Inc
Daniel Chase
V.P. Engineering & Operations
1331 Tyler St NE
Minneapolis, Minnesota 55413

Re: K143185
Trade/Device Name: entré Model PD08-U
Regulation Number: 21 CFR 870.5800
Regulation Name: Compressible Limb Sleeve
Regulatory Class: Class II
Product Code: JOW
Dated: March 27, 2015
Received: March 30, 2015

Dear Daniel Chase,

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)*
K143185

Device Name
entré Model PD08-U

Indications for Use *(Describe)*
The entré System is intended for use by medical professionals and patients who are under medical supervision, for the treatment of the following conditions:

- Chronic edema
- Lymphedema
- Venous insufficiency
- Wound healing

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: K143185

Submission Date: April 30, 2015

Submitter: Daniel G. Chase
VP, Engineering and Operations
Tactile Medical
1331 Tyler Street NE, Suite 200
Minneapolis, MN 55413 USA
Telephone: (612) 355-5133

Contact Person: Daniel G. Chase

Name of Device: entré Model PD08-U

Classification: Compressible Limb Sleeve (21 CFR 870.5800)

Predicate Devices: Petite Basic System 701 ELT (K131420)
CircuFlow 5150 (K123959)
CircuFlow 5208 (K123647)

Device Description

The entré model PD08-U system consists of two main components: A controller and a garment. The garment is to be wrapped around the affected extremity providing a snug yet comfortable fit. The garment will have eight (8) chambers that are filled with air by the controller to provide compression on the extremity. A harness assembly consisting of eight (8) individual tubes will connect individual chambers with the controller. The controller has an internal valve manifold with a directly connected single eight (8) port connector extension that is accessible to the user on the front panel allowing easy garment connection.

Intended Use

The entré System is intended for use by medical professionals and patients who are under medical supervision, for the treatment of the following conditions:

- Chronic edema
- Lymphedema
- Venous insufficiency
- Wound healing

Comparison of Technical Characteristics

The entré model PD08-U system has the same technological characteristics to the predicate devices with respect to intended use, design, materials used, and construction. The device has been certified to be compliant with ANSI/AAMI ES60601-1, IEC 60601-1 Ed. 3, CAN/CSA C22.2 No. 60601-1 (Medical Electrical Equipment- General require for Safety), EN 60601-1-2 (Electromagnetic Compatibility), IEC 60601-1-6 (Usability), and IEC 60601-1-11 (In-Home Medical Equipment).

Test Summary

The following performance testing and analysis was completed to verify the substantial equivalence between the entré model PD08-U, the subject of this submission, and the predicate devices.

- **Garment Chamber Pressure Testing**
  Both the entré model PD08-U and the predicate devices operate within similar pressure ranges. Pressure testing was performed to verify that the target pressures were met as stated in the device labeling.

- **Cycle Time Testing**
  Predicated devices and the entré model PD08-U are pressure based. Comparative cycle time data was recorded and evaluated. Both devices performed similarly and as stated in the device labeling.

- **Additional Testing**
  Additional non-clinical testing performed for the entré model PD08-U included:
  - Electromagnetic Safety (IEC 60601-1-2:2007)
  - Electrical Safety (IEC 60601-1:2005)

Substantial Equivalence Conclusion

The results from nonclinical device testing demonstrates that the entré model PD08-U system raises no new safety or effectiveness concerns and is substantially equivalent to the predicate devices for its intended use.