

510(k) Summary

JUN 18 2013

Submission Date: 25 April 2013Submitter: Dave Halverson
Sr. Quality Engineer
Tactile Systems Technology, Inc.
1331 Tyler Street NE, Suite 200
Minneapolis, MN 55413
Phone: (612) 355-5100Contact person: Dave HalversonName of Device: ACTitouch™ Adaptive Compression Therapy systemClassification: Compressible Limb Sleeve (21 CFR 870.5800)Predicate Device With Which Substantial Equivalence is Claimed:**Device Name:** Extremity Pump 7500**Company:** Jobst Institute**510(k) Number:** K882683**Classification:** Compressible limb sleeve (21 CFR §870.5800)Device Description:

The ACTitouch™ System applies compression to the leg (lower leg, ankle, and foot). It consists of four main parts:

- The Compression Sleeve consists of four chambers that inflate with air to apply pressure to the leg. It's simple wrap-around design with hook and loop fasteners means the Compression Sleeve can be fitted to many differently shaped legs and can be applied and removed with ease.
- The Control Unit fits into the Compression Sleeve during device use. It monitors and adjusts the air pressure to ensure the correct level of compression is applied to the leg.
- The Undersock is designed to draw perspiration and moisture away from the skin and has padding in key areas to provide additional comfort.
- The Power Adapter/Charger is used to power the device directly or to charge the battery for ambulatory use.

The device has two modes of operation: Sustained Compression Mode and Intermittent Pneumatic Compression Mode. Sustained Compression Mode enables the Control Unit to provide accurate and continuously monitored compression levels to the lower limb. Intermittent

Pneumatic Compression Mode enables a programmed sequence of cyclical pressures to be applied to the lower limb.

The ACTitouch™ system features a compliance monitoring feature. An LCD screen is present on the Control Unit, which displays the number of hours the device has been operational in both Sustained Compression Mode and Intermittent Pneumatic Compression Mode.

Intended Use:

The ACTitouch™ System provides optimized graduated compression in both sustained and intermittent settings for use in:

- Enhancing venous return
- Reducing venous leg ulcer healing time
- Treatment and promotion of healing of stasis dermatitis and venous stasis ulcers
- Treatment of chronic venous insufficiency
- Reducing edema due to venous stasis
- Treatment of lymphedema

The intended use and indications for use of the predicate device and the ACTitouch™ system are substantially equivalent.

Comparison of Technological Characteristics:

The ACTitouch™ system consists of a Control Unit, Compression Sleeve(s), an Undersock, and a Power Adapter/Charger. The various components of the ACTitouch™ system are supplied with a User Manual. The ACTitouch™ system can be powered by either the on-board battery for mobile use, or the supplied Power Adapter/Charger for use with Intermittent Pneumatic Compression Mode (when non-ambulatory). The ACTitouch™ system has two built-in safety mechanisms: software controlled pressure monitoring and control, and automatic shutdown and deflation. The ACTitouch™ system is substantially equivalent to the predicate device, with the added benefits of:

- Dual modality (Sustained Compression and Intermittent Pneumatic Compression modes)
- Four-chambered Compression Sleeve (extra chamber providing pressure to ankle region)
- Internal compression tubing, and an integral housing for the Control Unit in the Compression Sleeve (no need for external straps)
- Device auto-shutdown feature in event of fault

Summary of Tests:

No comparative testing has been performed between the ACTitouch™ system and Jobst Extremity Pump 7500, as per 807.92 (b) (1,2,3).



Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-002

June 18, 2013

Tactile Systems Technology, Inc.
c/o Dave Halverson
1331 Tyler Street NE, Suite 200
Minneapolis, MN 55413

Re: K131193
Trade/Device Name: ACTitouch
Regulation Number: 21 CFR 870.5800
Regulation Name: Compression Limb Sleeve
Regulatory Class: Class II
Product Code: JOW
Dated: April 25, 2013
Received: April 26, 2013

Dear Mr. Halverson:

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 Small Manufacturers, International and Consumer Assistance 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 Small Manufacturers, International and Consumer Assistance 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,

Bram D. Zuckerman -S

Bram D. Zuckerman, Ph.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number: K131193

Device Name: ACTitouch™ Adaptive Compression Therapy system

Indications for Use:

The ACTitouch™ Adaptive Compression Therapy system provides graduated compression in both sustained and intermittent settings for use in:

- Enhancing venous return
- Reducing venous leg ulcer healing time
- Treatment and promotion of healing of stasis dermatitis and venous stasis ulcers
- Treatment of chronic venous insufficiency
- Reducing edema due to venous stasis
- Treatment of lymphedema

Prescription Use X
(Part 21 CFR 801 Subpart D)

OR

Over the Counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Bram D. Zuckerman -S
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