K062818
Page 1 of 2

TACTILE SYSTEMS TECHNOLOGY INC.

Corporate Office
4824 Park Glen Road
Minneapolis, MN 55416

Phone 952.224.4060
Fax 952.224.4061
www.flexitouch.com

OCT - 6 2006

Aug 31, 2006

## SUMMARY OF SAFETY AND EFFECTIVENESS

This summary of safety and effectiveness is being submitted in accordance with the requirements of SMDA 1990.

Submitter: Phillip R. Rose
Director of Quality Systems and Regulatory Affairs
Tactile Systems Technology, Inc
4824 Park Glen Rd.
Minneapolis, MN 55416
Phone: (952)2244060 Fax: (952) 224-4061

Contact person: Phillip R. Rose

Name of Device: Flexitouch® System

Classification: Powered Inflatable Tube Massager, Class II

Predicate Devices: Bio Compression Systems, Inc. Model SC-3008 Sequential Circulator (K043423)

Medical Compression Systems Ltd ActiveCare®++ System (K060146)

Tactile Systems Technology, Inc. Flexitouch® System (K013061)

Description of Device:
The Flexitouch® System is a powered inflatable tube massager intended for medical purposes. The primary components of the System include a pneumatic sequential controller device that delivers air to garments with inflatable chambers to be worn over the patient's afflicted areas. The inflation and deflation of the chambers simulates kneading and stroking of the tissues with the hands in order to increase circulation.

SUMMARY OF SAFETY AND EFFECTIVENESS (continued)

Intended Use:
The Flexitouch system is intended for use by medical professional and patients at home who are under medical supervision in treating many conditions such as:

- Primary lymphedema
- Post mastectomy edema
- Edema following trauma and sports issues
- Post immobilization edema
- Venous insufficiencies
- Lymphedema
- Reducing wound healing time
- Treatment and assistance in healing: stasis dermatitis; venous stasis ulcers; arterial and diabetic leg ulcers

Comparison of Technological Characteristics:
The Flexitouch System is substantially equivalent to devices reviewed under FDA's product code JOW that have been cleared for the same intended use of primary or adjunctive treatment of primary or secondary lymphedema and venous insufficiency using the same technical technology. The predicates have also been cleared for treatment and assistance in healing: stasis dermatitis, venous stasis ulcers; arterial and diabetic leg ulcers and reducing healing time. The only reason for this submission is to include these indications for the device's use.

Performance Comparison:

Comparison of the functional and performance capabilities and specifications was made to the listed predicate devices and it is concluded that the device that is the subject of this 510(k) is substantially equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT - 6 2006

Tactile Systems Technology, Inc.
c/o Mr. Neil E. Devine, Jr.
Responsible Third Party Official
Intertek Testing Services NA, Inc.
2307 Aurora Road, Unit B7
Twinsburg, OH 44087

Re: K062818
Trade Name: Flexitouch® System
Regulation Number: 21 CFR 870.5800 and 21 CFR 890.5650
Regulation Name: Compressible Limb Sleeve
Regulatory Class: Class II (two)
Product Code: JOW and IRP
Dated: September 19, 2006
Received: September 20, 2006

Dear Mr. Devine:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Donna R. Vuchnes

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

Enclosure

# Indications for Use

510(k) Number (if known): K062818

Device Name: Flexitouch® System

Indications for Use:

The Flexitouch system is intended for use by medical professionals and patients who are under medical supervision, in treating many conditions such as:

- Primary lymphedema
- Post mastectomy edema
- Edema following trauma and sports injuries
- Post immobilization edema
- Venous insufficiencies
- Lymphedema.
- Reducing wound healing time
- Treatment and assistance in healing: stasis dermatitis; venous stasis ulcers; arterial and diabetic leg ulcers

| Prescription Use ____X___ (Part 21 CFR 801 Subpart D) | AND/OR | Over-The-Counter Use _____ (21 CFR 801 Subpart C) |
|---|---|---|

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

---

Concurrence of CDRH, Office of Device Evaluation (ODE)



Donna R. Vachney

**(Division Sign-Off)**
**Division of Cardiovascular Devices**

**510(k) Number** K062818