Section 2 - 510(k) Summary and Certification

[As required by 21 CFR 807.92(c)]

1. *Submitter's Name / Contact Person*

Eric McKee

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Tactile Systems Technology, Inc.
1074 Legion Street
Shakopee, MN 55379
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2. *General Information*

Trade Name: ***biotouch***™ Massage Therapy System

Classification Name: Massager, Powered Inflatable Tube

Classification: This device has been classified by the Division of Physical Medicine into Class II (21 CFR 890.5650) as a Massager, Powered Inflatable Tube

3. *Device Description*

The TSTI ***biotouch***™ device is a microprocessor controlled pneumatic compression device that applies calibrated sequentially graduated pressure to the arm, leg, trunk, and/or chest. The device consists of two major components:

- lightweight, portable pneumatic controller, and
- extremity garments composed of 4 to 16 chambers.

The controller is pre-programmed with thirteen separate treatment programs, which consists of pre-determined sequences and inflation times and should be used under medical supervision. The device is provided to the end-user in individual cartons to ensure safe shipping and arrival of the device. (See Attachment B for device drawings.)

4. *Intended Use*

The ***biotouch***™ device is intended for use by medical professionals and patients at home, who are under medical supervision, in treating many conditions, such as:

- Primary lymphedema
- Post mastectomy edema
- Edema following trauma and sport injuries
- Post immobilization edema
- Venous insufficiencies
- Lymphedema.

5. *Substantial Equivalence Comparison*

The ***biotouch***™ device is substantially equivalent to the following devices with respect to intended use, design, materials and construction:

- (Progressive Medical Technology, Inc., Multipulse Sequential Compression Unit (K914774))

No new safety and/or effectiveness issues are raised.

6. *Summary of Studies*

Performance testing was completed to verify the design specifications necessary for the ***biotouch***™ device. Test results support the safety and performance of the ***biotouch***™ device for its intended use.

7. *Conclusion (statement of equivalence)*

The data and information provided in this submission supports a substantial equivalence determination, and, therefore, 510(k) premarket notification clearance of the ***biotouch***™ device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 1 2002

Mr. Eric McKee
President
Tactile Systems Technology, Inc.
1074 Legion Street
Shakopee, MN 55379

Re: K013061
Trade/Device Name: biotouch™ Massage Therapy System
Regulation Number: 890.5650
Regulation Name: Powered inflatable tube massager
Regulatory Class: II
Product Code: IRP
Dated: April 12, 2002
Received: April 15, 2002

Dear Mr. McKee:

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 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained 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/dsma/dsmamain.html

Sincerely yours,

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

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- Post immobilization edema
- Venous insufficiencies
- Lymphedema.

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K013061

January 4, 2002