K092731

# 510(k) Summary

(per 21 CFR 807.92(c))

## 1. Applicant

Pneumex, Inc
2605 North Boyer Ave.
Sandpoint, ID 83864

JUN 10 2010

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Date Prepared: April 21, 2010

## 2. Device Name

| | |
|---|---|
| Device Name: | Vibro-Trac™ Table |
| Regulation Description: | Multi-Function Physical Therapy Table |
| Regulation Number: | 890.5880 |
| Product Code: | JFB |
| Device Class: | II |
| Review Panel: | Physical Medicine |

## 3. Predicate Devices

The Vibro-Trac™ Table is substantially equivalent to the following device:

| 510(k) Number | Device | Applicant |
|---|---|---|
| K063034 | Air-Flex with Auto Distraction | Hill Laboratories Co. |

## 4. Indications for Use

The Vibro-Trac™ is a multi-function physical therapy table intended for medical purposes that consists of a motorized table which can be equipped to provide patients with powered distraction and muscle relaxation therapy.

## 5. Description of the Device

The Pneumex Vibro-Trac™ is a Hi-Lo multifunction distraction/vibration table designed to apply distraction forces to a patient's spine, and to provide spinal muscle relaxation through vibration.

The patient lies in a supine position on the table with the knees bent and supported at a 90° angle (e.g., knees supported by an exercise ball). The patient wears an upper body harness, which is attached by shoulder straps and carabineers to the head traction bars at a location to provide greater or less tension, as determined by the medical practitioner. The patient wears a pelvic belt with two tensioning straps attached to either side. The pelvic belt allows for anterior, medial, and posterior force on right and left hip independently. The tensioning straps are attached to the foot traction bars and provide the required amount of tension, as determined by the medical practitioner.

## 6. Summary of the Technical Characteristics

The Vibro-Trac™ was tested in accordance with the medical electrical equipment requirements defined by:

- IEC 60601-1-2 for electromagnetic compatibility; and
- IEC/UL 60601-1 and CSA C22.2 No. 601.1 for electrical safety.

Finally, laboratory testing was conducted on the Vibro-Trac™ to ensure it would perform optimally during normal use.

## 7. Safety and Effectiveness

The Vibro-Trac™ is a safe and effective device and is substantially equivalent to the predicate device listed in this 510(k) submission; that is, the indications for use for the Vibro-Trac™ overlap that of the predicate device. In addition, the subject and predicate devices are similar in both design and function. Any differences in technological characteristics between the Vibro-Trac™ and the predicate device do not raise issues of safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

Conmed Corporation
% Emergo Group
Ms. Jean Asquith
Senior Regulatory Affairs Consultant
1705 S. Capital of Texas Highway, Suite 500
Austin, Texas 78746

JUN 10 2010

Re: K092731
Trade/Device Name: Vibro-Trac
Regulation Number: 21 CFR 890.5880
Regulation Name: Multi-function physical therapy table
Regulatory Class: II
Product Code: JFB
Dated: May 4, 2010
Received: May 4, 2010

Dear Ms. Asquith:

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.

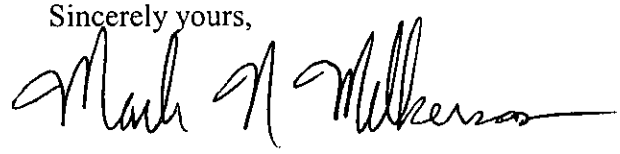
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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,



Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known): _____

Device Name: Vibro-Trac

Indications for Use:

The Vibro-Trac™ is a multi-function physical therapy table intended for medical purposes that consists of a motorized table which can be equipped to provide patients with powered distraction and muscle relaxation therapy.

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

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K092731