APR 21 2008

510(k) Summary

Submitted by: Daniel J. Manelli
Manelli & Fisher, P.L.L.C.
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Washington, DC 20015

Telephone: 202-885-5548

On behalf of Therapeutic Clinical Technologies, Inc.
2655 South Rainbow Blvd. (Ste. 300)
Las Vegas, Nevada 89146

510(k) Submission: GraviLax Traction Device
Date: March 27, 2008

Description:

The device is a powered traction device pursuant to 21 CFR 890.5900 (FDA product code ITH) class 2. The device is substantially equivalent to various other traction devices which achieve their effect through the force of gravity and/or mechanical means, including the following:

HangUps InvertAlign; STL International Inc. K991835;
BAX-D Genesis System; VAD-D Medical Technology Services, LLC. K053503;
Digit-Trac 930 Traction System; Ever Prosperous Instrument, Inc. K052453;
Extentrac Elite; Advanced Back Technologies, Inc. K031996; and
DRS System; Professional Distribution Systems, Inc. K981822.

Indications for Use: The GraviLax Traction System is intended for use in exerting therapeutic pulling force on the patient's body. The device utilizes a cylindrical hot tub in which the patient is supported vertically by a shoulder harness and which contains salt water whose salinity is adjusted to a specific gravity of approximately 1.2 providing an increased natural buoyancy to the user's body. Decompressive force (unloading due to distraction and positioning) to the sacral, lumbar and thoracic spine is achieved by application of suitable weights to the patient's ankles. This device is for prescription use only and is limited to use by qualified personnel in a suitably equipped treatment facility.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Therapeutic Clinical Technologies
% Manelli & Fisher, P.L.L.C.
Mr. Daniel J. Manelli
5335 Wisconsin Avenue, Suite 440
Washington, DC 20016

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Re: K072064
Trade/Device Name: GraviLax Traction System
Regulation Number: 21 CFR 890.5900
Regulation Name: Power traction equipment
Regulatory Class: Class II
Product Code: ITH
Dated: March 27, 2008
Received: March 28, 2008

Dear Mr. Manelli:

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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

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

Enclosure

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Exhibit A

Indications for Use

510(k) Number (if known): K072064

Device Name: GraviLax Traction System

Indications for Use:

The GraviLax Traction System is intended for use in exerting therapeutic pulling forces on the patient's body. The device utilizes a cylindrical hot tub in which the patient is suspended vertically by a shoulder harness and which contains salt water whose salinity is adjusted to a specific gravity of approximately 1.2 providing an increased natural buoyancy to the user's body. Decompressive force (unloading due to distraction and positioning) to the sacral, lumbar and thoracic spine is achieved by application of suitable weights to the patient's ankles This device is for prescription use only and is limited to use by qualified personnel in a suitably equipped treatment facility.

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)

Neil R Ogden for mxm

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

510(k) Number K072064