K110858

510(k) Summary

AUG - 2 2011

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Date Prepared: 3/17/2011

Device Name: *Lo-Bak TRAX*
Classification Name: Non-powered Orthopedic Traction Apparatus and Accessories (CFR) 888.5850, Type 1 device, Product Code: HST

Legally Marketed Predicate: Teeter Hang Up's Inversion Table. Model # EP550

Device Description: *Lo-Bak TRAX* is a non-powered, portable spinal traction device which is designed to simplify spinal traction of the lumbar spine and stretch the para-spinal soft tissues. It is light-weight (weighs less than 5 pounds) and compact, yet very strong and durable. Much like bicycle handlebars, there is a right and left handle. Correspondingly, there is a right and left thigh contact. The two thigh contacts are designed to align with the inguinal/thigh crease formed where the upper-most thigh attaches to the trunk when the hips are flexed 90 degrees. It has foam handle grips and ¼" SCE foam leg contact pads which both, provide comfort and function to prevent slippage while using the device. It is powder-coated with high gloss paint to make clean up easy with a warm, soapy cloth or disinfective wipe.
There are no moving parts and no assembly required. It is ready to use from the moment you take it out of the box.
This device is designed to traction the lumbar spine by utilizing the upper thighs as the contact point and the bilateral upper extremities as the traction force source. The device will accomplish this by having the user lie in a supine posture with the lower extremities flexed at both the hips and knees bilaterally with the heels positioned as close as comfortable to the corresponding buttock area. This posture flattens the lumbar lordosis, creating more of a straight line force vector which results in unweighting of the discs and facet joints while simultaneously relaxing the surrounding para-spinal musculature. This posture makes the spine more amenable to distraction with less force required than a device which attempts to traction the lumbar spine with the lumbar lordosis maintained.

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Once the thigh contact is made, the user pushes the handles towards the feet utilizing the upper extremities/body as the traction force source. This device and posture provides significant traction to the lumbar spine area without the need for any cables, pulleys, restraints or weights.

Because the device is user-controlled, the force utilized is totally under the control of the user. The hold time for the force is between 20-30 seconds at a time, and the protocol calls for 4-6 repetitions with a 90-120 second rest time in between repetitions for a total treatment time of between 10-15 minutes. This is an intermittent form of traction. The user will feel when too much force is being applied and is ultimately the best judge of how much force they can tolerate on a specific day. The user is in total control at all times of the amount of force applied and even, the direction of the force. The direction can be varied by the user to affect not only different levels of the spine, but from right to left as well, simply based upon where the thigh contacts are placed and how much force is applied to either handle. The energy supplied is all based upon the user's own upper body strength.

Indications for Use:
Lo-Bak TRAX is intended for single person use by adults to provide portable, non-powered traction force to the lumbar spine and to stretch and relax the para-spinal muscles and soft tissues.

Use of *Lo-Bak TRAX* is indicated for the following conditions: *low back pain, degenerative disc disease, spinal degenerative joint disease, spinal stenosis, herniated disc, spinal curvature due to tight muscles, sciatica and muscle spasm.*

Technological Characteristics Similarities vs. Differences:

***Lo-Bak TRAX* and Predicate Device Similarities:**

- Both are Non-powered, Non-invasive Orthopedic Traction Devices.
- Both target the spine with their treatment.
- Both cause unweighting of the intervertebral discs and facet joints due to distraction and positioning.
- Both stretch and relax the muscles and soft tissues surrounding the spine.
- Both naturally target low back pain and its associated disability without the need for complimentary modalities.
- Both are user controlled.
- Both are designed for home use by adults, without the need for supervision.

Lo-Bak TRAX and Predicate Device Differences:

Device & Predicate Device(s):	K110858 Lo-Bak TRAX	Teeter Hang Ups Inversion Table Model 550 (Exempt) From website
Physical Attributes & Indicators:		
Basic Materials	Powder-coated metal tubing, foam hand grips and pads, stainless steel thigh contacts	Powder coated metal tubing, rubber coated hand grips, sling surface of unknown material
Measurements and Weight	23" x 9" x 4" 3.5lb's	48" x 27" x 61" 68lb's
Treatment Position	Supine, with hips flexed approx 80 deg. and feet resting flat	Supine with ankles secured – variable degree of inversion. Legs extended.
Method of Generating Traction Force	Pressure exerted by user's upper extremities pushing on handle bars, with bilateral upper thighs as contact points	Gravity assisted by variable degrees of inversion (up to full inversion)
Amount of Traction Force Supplied	Variable – based on force exerted by user	Variable – based on degree of inversion – body weight + gravity assist
Force Gauge	No	No
Assembly Required by User	No	Yes

Lo-Bak TRAX is designed to be lightweight and portable.

Lo-Bak TRAX is designed to utilize a supine lying posture for comfort, effectiveness and safety.

Lo-Bak TRAX is designed to utilize user generated and controlled intermittent type traction.

Lo-Bak TRAX is designed with no moving parts or assembly required and is ready to use from the moment it is taken out of the box.

Summary of safety and effectiveness:

Lo-Bak TRAX was designed to address the need for a portable, simple to use, safer way of tractioning the lumbar spine while maintaining the effectiveness of such a device.

Lo-Bak TRAX's new approach to lumbar spine traction does not adversely affect safety or effectiveness as compared to the predicate device.

The important attributes contributing to the safety and effectiveness of *Lo-Bak TRAX* include: the user controlled force source with no reliance on mechanical involvement to initiate, the new biomechanical postural approach designed to maximize comfort while minimizing the force necessary to achieve unweighting of the discs and facet joints while simultaneously stretching and relaxing the para-spinal soft tissues, the intermittent form of traction, and it's one piece design with no moving parts.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

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Re: K110858
Trade/Device Name: Lo-Bak TRAX
Regulation Number: 21 CFR 888.5850
Regulation Name: Nonpowered orthopedic traction apparatus and accessories
Regulatory Class: Class I
Product Code: HST
Dated: July 25, 2011
Received: July 28, 2011

Dear Dr. Berthiaume:

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

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Prescription Use_____ AND/OR Over-The-Counter Use____X____
(Part 21 CFR 801 Subpart D) (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)

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

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