DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

December 30, 2016

STL International, Inc.
% Korina Akhondzadeh
Regulatory Consultant to STL International, Inc.
Kara & Associates
6965 El Camino Real
Suite 105-428
Carlsbad, California 92009

Re: K162702
Trade/Device Name: Teeter Manual Inversion Table; Teeter Gravity Boots; Teeter Forward Rotation Decompression Device; Teeter Portable Decompression Device; Teeter Horizontal Decompression Table
Regulation Number: 21 CFR 888.5850
Regulation Name: Nonpowered Orthopedic Traction Apparatus and Accessories
Regulatory Class: Class I
Product Code: HST
Dated: December 02, 2016
Received: December 05, 2016

Dear Korina Akhondzadeh:

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 contact the Division of Industry and Consumer Education 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. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 Industry and Consumer Education 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,

Michael J. Hoffmann -S

for Carlos L. Peña, PhD, MS
Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K162702

Device Name
Teeter Manual Inversion Table;
Teeter Gravity Boots;
Teeter Forward Rotation Decompression Device; Teeter Portable Decompression Device; Teeter Horizontal Decompression Table

Indications for Use *(Describe)*
Teeter Decompression Devices are multiple user, reusable devices for home use, intended to provide traction to the spine while stretching the para-spinal muscles and soft tissues. The devices provide non-powered traction and are meant for use by adults.

Use of the Teeter Decompression Devices is indicated for the following conditions: back pain, muscle tension, degenerative disc disease, spinal degenerative joint disease, spinal stenosis, herniated disc, spinal curvature due to tight muscles, sciatica, muscle spasm, and facet syndrome.

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary – K162702

This 510(k) summary is being submitted in accordance with the requirements of 21 CFR 807.92.

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Date Prepared: December 29, 2016

II. DEVICE

Device Name:	Teeter Decompression Devices
Common/Usual Name:	Apparatus, Traction, Non-Powered
Regulation:	21 CFR 888.5850
Classification Name:	Nonpowered Orthopedic Traction Apparatus and Accessories
Product Code:	HST
Class:	I

III. PREDICATE DEVICE

Predicate Device Lo-Bak TRAK, K110858

This predicate device has not been subject to a recall.

IV. DEVICE DESCRIPTION

Teeter's decompression devices are designed to decompress the spine and stretch para-spinal soft tissues. The devices are non-powered, external (non-invasive) and user-controlled. Decompression is accomplished in various ways depending on the model within the Teeter product family.

The inversion type devices, which are illustrated below, decompress the spinal region with the weight of the upper body, (angle only applies to the manual table, the others only offer full inversion – so variable loads are not an option)

Manual Inversion Table – Supporting the user at the ankles, the device enables the user to rotate into the inverted position and allows the user to maintain a relaxed state as their body weight combined with the downward force of gravity creates progressive traction, decompressing each joint by the same weight that compresses it while upright. The user is able to predetermine or stop at their chosen degree of rotation, allowing increasing stretching intensity as the angle of inversion advances.

Manual Inversion Table

Gravity Boots – Supporting the user at the ankles, the device enables the user to hang in the inverted position, keeping the user relaxed while their body weight combined with the downward force of gravity creates progressive traction, decompressing each joint by the same weight that compresses it while upright.

Gravity Boots

Forward Rotation Decompression Device – The user leans over a foam lap pad, supported at their upper thighs, to rotate forward on the device into an inverted position while bending the knees behind a roller for support. The lap pad and foam rollers provides a contact support, holding the user in the inverted position. The hips and knees

are flexed 90 degrees, placing the body in a position that flattens the lumbar curve, increasing muscle relaxation and decompression of the spine.

Forward Rotation Decompression Device

The manual traction devices, which are illustrated below, apply decompression to the spinal region by applying force with the bilateral upper extremities on the device's handlebars while the user's legs are secure and stationary.

Portable Decompression Device – While seated on a flat surface, the user positions the device so the left and right thigh contacts align with upper-most thigh area and the foam roller contacts are behind the knees. The user reclines into the supine position, with knees and hips at 90°, flattening the lumbar curve to increase muscle relaxation and decompression of the lumbar spine once the device is utilized. The contacts provide leverage at the front and back of the thighs so that when the user pushes with their hands on the handles toward the feet, straightening their arms and applying self-controlled traction force to decompress the lumbar and mid-spine.

Portable Decompression Device

Horizontal Decompression Device – Laying in the supine position with knees bent at 90°, with supports under the armpits and behind the knees, the user pushes with their hands on the handles toward the feet. This causes the device to separate at the mid-point, pushing against the knees to pull the lower body away from the head and deliver traction to the lumbar and mid-spine.

Horizontal Depression Table

All Teeter Decompression Devices are made of rigid, powder coated steel, plastic and foam, requiring little or no regular maintenance and allowing for easy product care. The devices allow the user to apply traction and control the force without use of mechanical weights, pulleys or weights.

V. INDICATIONS FOR USE

Teeter Decompression Devices are multiple user, reusable devices for home use, intended to provide traction to the spine while stretching the para-spinal muscles and soft tissues. The devices provide non-powered traction and are meant for use by adults.

Use of the Teeter Decompression Devices is indicated for the following conditions: back pain, muscle tension, degenerative disc disease, spinal degenerative joint disease, spinal stenosis, herniated disc, spinal curvature due to tight muscles, sciatica, muscle spasm, and facet syndrome. Type of Use: Over-the-Counter Use

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

Both the Teeter Decompression Devices and the predicate Lo-Bak TRAX are non-powered traction devices used to provide traction to the lumbar spine while stretching the para-spinal muscle and soft tissues. Refer to the following table for comparison of the technological characteristics with the Teeter Decompression Devices and the predicate.

Characteristic	Teeter Decompression Devices					Lo-Bak TRAX **(Predicate)** K110858
	Manual Inversion Table	Gavity Boots	Forward Rotation Decompression Device	Portable Decompression Device	Horizontal Depression Table	
Traction Type	Non-Power	Non-Power	Non-Power	Non-Power	Non-Power	Non-Power
Product Type	Inversion	Inversion	Inversion	Manual	Manual	Manual
Treatment Position	Inverted at various angles	Inverted at various angles	Inverted at various angles	Supine	Supine	Supine
Method of generating decompress-	Gravity and weight of	Gravity and weight of	Gravity and weight of upper body	Upper bilateral extremities with lower	Upper bilateral extremities	Upper bilateral extremities

Characteristic	Teeter Decompression Devices					Lo-Bak TRAX **(Predicate)** K110858
	Manual Inversion Table	Gavity Boots	Forward Rotation Decompression Device	Portable Decompression Device	Horizontal Depression Table	
sion force	upper body	upper body		extremities secure and stationary	with lower extremities secure and stationary	with lower extremities secure and stationary
Amount of force applied	Variable – Based on upper body weight and angle of inversion	Variable – Based on upper body weight and angle of inversion	Variable - Based on upper body weight and angle of inversion	Variable – Based on force exerted by user	Variable – Based on force exerted by user	Variable – Based on force exerted by user
Frame construction	Powder-coated steel	Powder-coated steel	Powder-coated steel	Powder-coated steel	Powder-coated steel	Powder-coated steel
Height Range	56-78”	None	56-78”	None	78”	None
Weight Limit	300 lb.	250 lb.	300 lb.	None	300 lb.	None

VII. SAFETY AND EFFECTIVNESS

The manual traction Teeter Decompression Devices have the same treatment position and generating the decompression forces in the same method. The difference in treatment position and the method of generating the decompression forces in the inversion type Teeter Decompression Devices does not affect the effectiveness and safety as it relates to the predicate device. Inversion decompression devices have been in use since the 1960’s and are a commonly accepted form of traction. However, it is important for the users to read the “Instructions of Use” document to ensure that specified requirements (e.g., weight, height) are met.

The amount of decompression force that is applied to the user is controlled by the user.

VII. PERFORMANCE DATA

The following evaluations were conducted on the Teeter Decompression Devices:

- Safety evaluations (Inversion table and gravity boots only)
- Risk analysis

VIX. CONCLUSIONS

Based on the information submitted in the 510(k) application, Teeter Decompression Devices are as safe and effective as the legally marketed device (i.e., Lo-Bak TRAX) device.