



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

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,

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

Enclosure

## Indications for Use

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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# EU DECLARATION OF CONFORMITY

Teeter Fitness Equipment Technical  
Documentation

Person Responsible for Regulatory Compliance: Angela Hawkins  
[ahawkins@teeter.com](mailto:ahawkins@teeter.com)



STL International Ltd.; DBA Teeter

22503 97th St E D, Bonney Lake, WA 98391  
FED ID# - 91-1361932

# EU Declaration of Conformity

## 1 MANUFACTURER INFORMATION

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- **Manufacturer Name:** STL International, Inc.; DBA-Teeter
- **Registered Trade Name:** Teeter
- **Address:** 22503 97th St E D, Bonney Lake, WA 98391
- **SRN:** US-MF-000024237
- **Contact Info:** [ahawkins@teeter.com](mailto:ahawkins@teeter.com) (Compliance Officer)

[Dolson@teeter.com](mailto:Dolson@teeter.com) (Additional Contact)

## 2 AUTHORIZED REPRESENTATIVE INFORMATION

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- **Authorized Representative Name:** MDSS GmbH
- **Contact Info:** [info@mdssar.com](mailto:info@mdssar.com)
- **Address:** Schiffgraben, 41 30175 Hannover
- **SRN:** DE-AR-000005430

## 3 STATEMENT OF RESPONSIBILITY

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This declaration of conformity is issued under the sole responsibility of the manufacturer, STL International, Inc.; DBA-Teeter.



## 4 PRODUCT IDENTIFICATION

Teeter Inversion tables are unambiguously identified by looking at the serial label on the back of every Teeter inversion table bed frame. All inversion table products use the serial label layout shown below.

Labeler	Device	Basic UDI	UDI		
			UDI-DI	UDI-PI	
				Serial label	Manufacture Date
Teeter	EP-560	0759265EP560RJ	00759265005601	xxxxxx	YYMMDD
Teeter	X3	0759265X3AER	00759265000033	xxxxxx	YYMMDD
Teeter	LX9	0759265LX9FT	00759265000002	xxxxxx	YYMMDD
Teeter	X2	0759265X2TS	00759265000026	xxxxxx	YYMMDD
Teeter	X1	0759265X1TQ	00759265000040	xxxxxx	YYMMDD
Teeter	DEX II	0759265DEXIIXA	00759265000019	xxxxxx	YYMMDD

Figure 1: Product Identification Table

## 5 USAGE CLASS H

Inversion tables usage class is “Class H” according to ISO 20957-1 section 4.3.2 because they are meant to be used in private homes where access to equipment is regulated by the owner.

## 6 CONFORMITY STATEMENT

The devices covered by this declaration are in conformity with Regulation (EU) 2017/745 on medical devices.

## 7 REFERENCES TO COMMON SPECIFICATIONS (CS)

Teeter's spinal decompression products exclusively comply with the EU Medical Device Regulation (MDR) 2017/745 Harmonized Standard as it provides a comprehensive framework that encompasses all necessary aspects of bringing a safe medical device to the European Market. The MDR mandates the implementation of a robust Quality Management System (QMS) and stringent risk management processes. Additionally, the MDR's detailed General Safety and Performance Requirements (GSPRs) ensure that our devices are designed and manufactured to the highest



standards of safety and effectiveness. The regulation's rigorous documentation requirements and post-market surveillance obligations further reinforce our commitment to maintaining the highest level of regulatory compliance and patient safety. By adhering to the MDR, we ensure that our products meet all relevant safety and performance criteria, providing confidence to regulators, healthcare professionals, and end-users.

## 8 NOTIFIED BODY INVOLVEMENT

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Pursuant to Article 52 Conformity Assessment Procedures Section 7;

*"7. Manufacturers of class I devices, other than custom-made or investigational devices, shall declare the conformity of their products by issuing the EU declaration of conformity referred to in Article 19 after drawing up the technical documentation set out in Annexes II and III. If those devices are placed on the market in sterile condition, have a measuring function or are reusable surgical instruments, the manufacturer shall apply the procedures set out in Chapters I and III of Annex IX, or in Part A of Annex XI. However, the involvement of the notified body in those procedures shall be limited: ..."*

Teeter Inversion tables and DEX II Spinal Decompression devices, which are non-invasive devices that are intended to relieve physical pressure of the spine, are classified as Class I medical devices. For Class I medical devices, the involvement of a Notified Body is not required if the device does not have a measuring function and is not sterile. Manufacturers of Class I devices must register themselves and their devices with the relevant national competent authority and ensure compliance with the MDR by preparing the appropriate Technical Documentation and implementing a Quality Management System that is compliant to Annex II and Annex III. This process involves self-declaration of conformity without the need for a Notified Body. This self-declaration is completed by the quality manager after a comprehensive conformity assessment.

## 9 ADDITIONAL INFORMATION

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Not applicable

## 10 PLACE AND DATE OF ISSUE

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- **Place:** Headquarters of STL International, Inc.; DBA-Teeter  
22503 97th St E D, Bonney Lake, WA 98391
- **Date:** March 31<sup>st</sup>, 2026
- **Name:** Angela Hawkins
- **Function:** Person Responsible for Regulatory Compliance,
- **On behalf of:** STL International, Inc.; DBA-Teeter
- **Signature:** 