Product Classification

New Search Back To Search Results

Device	Table, Powered
Regulation Description	Powered table.
Regulation Medical Specialty	Physical Medicine
Review Panel	Physical Medicine
Product Code	INQ
Submission Type	510(K) Exempt
Regulation Number	890.3760
Device Class	1
Total Product Life Cycle (TPLC)	TPLC Product Code Report
GMP Exempt?	No

Note: FDA has exempted almost all class I devices (with the exception of reserved devices) from the premarket notification requirement, including those devices that were exempted by final regulation published in the *Federal Registers* of December 7, 1994, and January 16, 1996. it is important to confirm the exempt status and any limitations that apply with 21 CFR Parts 862-892. Limitations of device exemptions are covered under 21 CFR XXX.9, where XXX refers to Parts 862-892.

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Guidance Document

- Guidance Document for the Preparation of Premarket Notification [510(k)] Applications for Powered Tables and Multifunctional Physical Therapy Tables

Third Party Review	Not Third Party Eligible

Page Last Updated: 12/05/2011

K091540

OCT - 8 2009

510(k) SUMMARY STATEMEMT

Mettler Traction Device, MTD 4000

Submitter's Name: Mettler Electronics Corp.
Address: 1333 South Claudina Street
Anaheim, CA 92805

Telephone: 714-533-2221 x324
Fax: 714-533-3860

Contact: Robert E. Fleming
Director, QA/RA

Date Prepared: May 21, 2009

Proposed Device Name:

a. TRADE NAME: MTD 4000
b. CLASSIFICATION NAME: Equipment, Traction, Powered (Sec. 890.5900, Product Code ITH)
c. COMMON NAME: Powered Traction Device

Predicate Devices:

a. TRADE NAME: Triton/Tru-Trac/TX/Triton DTS Traction Device by Chattanooga.
b. 510(k) Number: K053223
c. TRADE NAME: TM-300 by ITO Co., Ltd.
d. 510(k) Number: K992545

Description of Proposed Device:

The MTD 4000 (Mettler Traction Decompression) system is an easy to use device that offers static and intermittent traction with user definable hold, rest, and treatment times. It gently pulls the cervical spine or lumbar spine in opposite directions to draw the soft tissue around the cervical or lumbar joints and separate the distance between bone sections of the vertebra.

The MTD 4000 may be used to help relieve peripheral radiation/sciatica and pain associated with: protruding discs, spinal root impingement, bulging discs, hypomobility, herniated discs, degenerative joint disease, degenerative disc disease, facet syndrome, posterior facet syndrome, compressions fracture, acute facet problems, radicular pain, discogenic pain and prolapsed discs.

Some of the features of the MTD 4000 are:

- Easy to use
- Active displays show all treatment parameters and progress.
- Multiple sensors and safety controls
- High strength traction cable
- Adjustable Hold/Rest times
- Continuous and Intermittent traction with multiple speed selection
- Smooth, quiet operation

Proposed Device Intended Use Statement:

The MTD 4000 traction device provides traction and mobilization of skeletal structures and skeletal muscles.

The MTD 4000 may be used to relieve peripheral radiation/sciatica and pain associated with:

- Protruding discs
- Bulging discs
- Herniated discs
- Degenerative disc disease
- Posterior facet syndrome
- Acute facet problems
- Radicular pain
- Prolapsed discs
- Spinal root impingement
- Hypomobility
- Degenerative joint disease
- Facet syndrome
- Compressions fractures
- Joint pain
- Discogenic pain

Comparison of Technological Characteristics Between Proposed and Predicate Devices:

Similarities:

1. Indications for use for the MTD 4000, and the aforementioned predicates are essentially the same, all related to powered traction treatment.
2. All have similar operating modes.
3. Each is provided with similar accessories.

Differences:

1. Physical shape and size of the enclosure.
2. Configuration of user interface controls.
3. Display methods.

Comparison Table

Feature	MTD 4000	Triton / Tru-Trac / TX Traction	TM-300
Distributor / Manufacturer	Mettler Electronics	Chattanooga Group	Ito Co., Ltd.
510k		K051938	K992545
Mains Supply	AC 110~120 / 220~240 V 50/60 Hz	100~240V / 50/60 Hz	AC 110~120/220~240 V 50/60 Hz
FDA Class	II	II	II
CE Classification	Class IIa, Type BF MDD 93/42/EEC	Class 1, Type B MDD 93 /42 /EEC	Class I, Type B
CE Mark	CE 0434	CE 0413	CE (MDD)
Dimensions (in)	12.2(W) x 14.2(D) x 9.1(H)	9.5(W) x 17.5(D) x 17.5(H)	10.2(W) x 13(D) x 9.8(H)
Weight (pounds)	32	30	26
User interface	Membrane, control knob	Touch screen, buttons	Membrane
Patient safety switch	Yes	Yes	Yes
Treatment Time (min)	1-99	1-99	1-99
Hold Time (sec)	0-99	0-99	1-99
Hold Force (lbs)	7-198	0-200	2-198
Rest Time (sec)	0-99	0-99	1-99
Rest Force (lbs)	0-196	0-200	0-196 lb

DEPARTMENT OF HEALTH & HUMAN SERVICES

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

Mettler Electronics, Corporation
% Mr. Robert E. Flemming
Director, QA/RA
1333 South Claudina Street
Anaheim, California 92805

OCT - 8 2009

Re: K091540
Trade/Device Name: MTD 4000
Regulation Number: 21 CFR 890.5900
Regulation Name: Power traction equipment
Regulatory Class: II
Product Code: ITH
Dated: August 18, 2009
Received: August 19, 2009

Dear Mr. Flemming:

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.

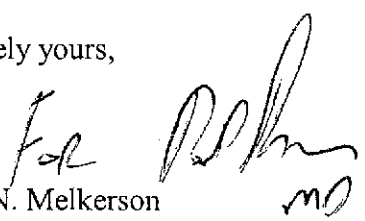
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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 (240) 276-3150 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

510(k) Number (if known): _____

Device Name: MTD 4000

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- Prolapsed discs
- Spinal root impingement
- Hypomobility
- Degenerative joint disease
- Facet syndrome
- Compressions fractures
- Joint pain
- Discogenic pain

FOR M. MELKERSON

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

510(k) Number K091540

Prescription Use X AND/OR Over the Counter Use _____
(Per CFR 801 Subpart D) (Per 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)

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DEPARTMENT OF HEALTH & HUMAN SERVICES

FOOD AND DRUG ADMINISTRATION

PHILADELPHIA DISTRICT

900 U.S. Customhouse
2nd and Chestnut Streets
Philadelphia, PA 19106

Telephone: 215-597-4390

March 12, 2013

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Geoffrey T. Miscoe, Owner
Mir-Com Products LLC
299 Main Street
Central City, PA 15926

Dear Mr. Miscoe:

As per our phone conversation this afternoon, our Office of Device Evaluation, Center for Devices and Radiological Health, Food and Drug Administration has determined that the combination device, MTD4000/Armedica Traction Table does not require a 510k. The addition of the table does not significantly change the design, components, method of manufacture or intended use of the MTD4000 device.

Sincerely,

Yvette Johnson

Yvette Johnson
Compliance Officer
Philadelphia District Office