510(k) Summary
clTrac
K222912

1. Basic Information-Submitter:

510(k) Owner:

Zimmer MedizinSysteme GmbH
Junkersstrasse 9
89231 Neu-Ulm
Germany
Establishment Registration: 8010720

Ms. Ute Killet
Manager Regulatory Affairs
Phone: +49-731-9761-216
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Official Correspondent:

Scott Blood
Principal Consultant
Phone: 978.729.5978
Fax: +49 731 9761 118
E-Mail: scottqara@gmail.com

Date Summary Prepared: May 11, 2023

2. Device Name:

Trade Name:	clTrac
Common Name:	Equipment, Traction, Powered
Classification Name:	Power traction equipment
Regulation Number:	21 CFR 890.5900
Product Code:	ITH
Classification:	Class II

3. Predicate Device: Eltrac 471 – K151640
   Company Name: Enraf-Nonius B.V.

4. Device Description:

The clTrac is powered traction equipment that offers both static and intermittent traction. Spinal traction is a form of decompression that relieves the pressure on the spine. Traction is a non-surgical, non-invasive and non-pharmaceutical treatment for the management of pain and symptoms from a variety of pressures on muscular or skeletal structures

The clTrac is intended to be used by healthcare professionals (HCP) on their patients. When device is operational, the applied force shall not exceed +/-10% of the target force as set by the operator. clTrac applies a specific force onto the traction cord. The applied force is set by the operator by means of the touch screen and rotary knob. A patient interrupt button is available for the patient to pause the therapy.The cl***Trac*** is a non-invasive therapeutic device.

The device consists of a console with ABS housing. The console consists of an aluminium ground plate, an ABS outer shell, a 7" touch screen and a steel central control knob. A 2.9m long cord with a plastic patient interrupt button is plugged into the console. The console is intended to be fastened to a standardized traction table using screws that are tightly screwed into its aluminium ground plate, with holes in a standardized pattern. The implemented motor-gear unit applies traction via a traction cord that is fixed into the console with a 360° swivel head with guide pulley. The traction cord is intended to be attached to hip and thoracic traction belts that are sold separately.

Indications for Use Statement:

cl***Trac*** is intended to provide relief for the management of pain and symptoms from a variety of pressures on muscular or skeletal structures. cl***Trac*** may be used to treat pain and symptoms associated with the following conditions: herniated discs, bulging or protruding intervertebral discs, degenerative disc disease, posterior facet syndrome, acute facet problems, radicular pain, prolapsed discs, spinal root impingement, hypomobility, degenerative joint disease, facet syndrome, compression fractures, joint pain, and discogenic pain.

ATTRIBUTE	**SUBJECT DEVICE** **Zimmer MedizinSystems GmbH** cl***Trac*** **K222912**	**PREDICATE DEVICE** **Enraf-Nonius B.V.** **Eltrac 471** **K151640**
	Physical Medicine Devices 21 CFR 890.5900 ITH – Equipment, Traction, Powered	Physical Medicine Devices 21 CFR 890.5900 ITH – Equipment, Traction, Powered
Indications for Use	cl***Trac*** is intended to provide relief for the management of pain and symptoms from a variety of pressures on muscular or skeletal structures. cl***Trac*** may be used to treat pain and symptoms associated with the following conditions: herniated discs, bulging or protruding intervertebral discs, degenerative disc disease,	The ELTRAC 471 Traction device, with its accessories, is intended to provide relief for the management of pain and symptoms from a variety of pressures on muscular or skeletal structures. The ELTRAC 471 Traction device may be used to treat pain and symptoms associated with the following conditions: herniated discs, bulging or protruding intervertebral discs, degenerative disc disease, posterior facet

ATTRIBUTE	SUBJECT DEVICE Zimmer MedizinSystems GmbH cl*Trac* K222912	PREDICATE DEVICE Enraf-Nonius B.V. Eltrac 471 K151640
	posterior facet syndrome, acute facet problems, radicular pain, prolapsed discs, spinal root impingement, hypomobility, degenerative joint disease, facet syndrome, compression fractures, joint pain, and discogenic pain.	syndrome, acute facet problems, radicular pain, prolapsed discs, spinal root impingement, hypomobility, degenerative joint disease, facet syndrome, compression fractures, joint pain, and discogenic pain.

The Indications for Use statement for cl***Trac*** is identical to the predicate device.

5. Technological Characteristics:

Both devices provide the traction therapy via a software-controlled motor to the traction cord that is connected to harness/belts that the patient wears. Both devices have a patient interrupt button in place ensuring that the therapy de-activates when the patient presses the button. In addition, treatment times are limited. Additionally, the therapy only starts if the patient interrupt button has been pressed at the cl***Trac*** device.

Both devices have an electrical input of 100 – 240 V AC, 50/60 Hz. Both devices employ software with touch-screen control to adjust settings and store treatment protocols.

Technological Characteristics	SUBJECT DEVICE Zimmer MedizinSystems GmbH cl*Trac* K222912	PREDICATE DEVICE Enraf-Nonius B.V. Eltrac 471 K151640
Design	Traction therapy utilize a software controlled motor to deliver force via a cord and harness to apply traction to the patient.	Traction therapy utilize a software controlled motor to deliver force via a cord and accessories to apply traction to the patient.
Display	Display with touch screen & central knob	Display with touch screen
Conditions of use	The device is intended for use by health care professional users only.	The device is intended for use by professional users only.
Technology	Setting of treatment parameters via a touch screen and central control knob.	Setting of treatment parameters via a touch screen.
	Therapy start, pause and stop with buttons on touch screen.	Therapy start, pause and stop with buttons on touch screen.

Technological Characteristics	SUBJECT DEVICE Zimmer MedizinSysteme GmbH cl*Trac* K222912	PREDICATE DEVICE Enraf-Nonius B.V. Eltrac 471 K151640
	Patient interrupt button to interrupt therapy at any time.	Patient stop switch to interrupt therapy at any time.
	Therapy only starts if the patient interrupt button has been connected and button has been pressed.	Treatment will not start if patient stop is not connected.
Power supply	100 – 240 V AC, 50/60Hz	100 - 240 V, 50/60 Hz
Traction tension	15 – 900 N	Not publicly available
Traction modes	Static Intermittent	Not publicly available
Storage treatment protocols	Yes A treatment protocol can be stored on the "Favorites" screen.	Yes A treatment protocol can be stored into the device's memory.
Traction Time	1 – 99 minutes	to 150 minutes
System stops & alerts	cl***Trac*** is designed with safety/warning features so that cervical traction treatment decisions are made with care. In addition, treatment times are limited, treatment will not start if the patient interrupt button in not connected and pressed. The patient is able to stop the treatment at any time by clicking on the patient interrupt button during a treatment a pop-up will show on the screen, accompanied by and acoustic signal. The treatment will be paused, the force will be reduced to 10N. Furthermore, an automatic system stop if the tension sensors detect inappropriate tension or the measurement results of the 2 tensions sensors are not identical.	Eltrac 471 is designed with safety/warning features so that traction treatment decisions are made with care. Treatment will not start if patient stop is not connected. In addition, treatment times are limited, and the patient is able to stop the treatment at any time with a switch. If it is pressed, the force will lower.
Principal of operation	Processor on main board to control step motor that applies traction to traction cord	A software controlled motor delivers force via cord
	Traction is delivered via traction cord that is connected to traction harness	Traction is delivered via traction cord that is connected to accessories

There are no significant technological differences between the cl***Trac*** device and the predicate device. There are few and not significant technological differences between the subject device and the predicate device. Those differences have been discussed and do not affect device safety or performance. The subject device has all features of the predicate device. cl***Trac*** does not raise any new types of safety or effectiveness questions.

6. Performance data

The cl***Trac*** device has been investigated and tested against and complies with the following voluntary standards:

Standards	Standards Organization	Standards Title
ES60601-1:2005/(R)2012 and A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012 (Consolidated Text)	ANSI AAMI	Medical electrical equipment – Part 1: General requirements for basic safety and essential performance
60601-1-2:2014 (Edition 4.0)	IEC	Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic disturbances – Requirements and tests
60601-1-6:2013 (Edition 3.1)	IEC	Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
62366-1:2015 (Edition 1.0)	IEC	Medical devices – Part 1: Application of usability engineering to medical devices
62304:2015 (Edition 1.1)	IEC	Medical devices software –software life cycle processes
14971:2019 (Edition 3.0)	ISO	Medical devices – Application of risk management to medical devices
15223-1:2016 (Edition 3)	ISO	Medical devices – Symbols to be used with medical device labels, labeling, and information to be supplied – Part 1: General requirements
10993-1:2018 (Edition 5)	ISO	Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process

The following table shows a comparison of the performance testing in comparison to the predicate device:

Standards	SUBJECT DEVICE Zimmer MedizinSysteme GmbH cl*Trac* K222912	PREDICATE DEVICE Enraf-Nonius B.V. Eltrac 471 K151640
ANSI AAMI ES60601-1	X	X
IEC 60601-1-2	X	X
IEC 60601-1-6	X	Not publicly available
IEC 62366-1	X	Not publicly available
IEC 62304	X	X
ISO 14971	X	X
ISO 10993-1	X	Not publicly available

According to this comparison table all required performance tests were conducted and show substantial equivalence with the predicate devices. cl***Trac*** has been designed and tested more, recently, so newer standards and additional standards are used to support 510(k).

Testing has been performed and all components, subassemblies and/or full devices and systems have met the required specifications for the completed tests.

7. Clinical Performance:

Not applicable. This device does not require clinical testing for demonstration of substantial equivalence and safety/effectiveness.

8. Conclusion:

Zimmer MedizinSysteme GmbH has demonstrated that the cl***Trac*** device is substantially equivalent to the predicate device.

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.

if a manufacturer's device falls into a generic category of exempted class I devices as defined in 21 CFR Parts 862-892, a premarket notification application and fda clearance is not required before marketing the device in the u.s. however, these manufacturers are required to register their establishment. please see the registration and listing website for additional information.

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.

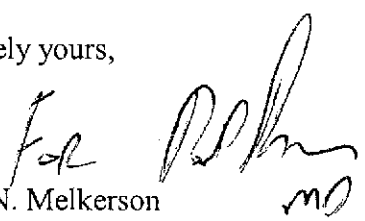
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further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

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

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)

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
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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

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