May 16, 2023

Zimmer MedizinSysteme GmbH
% Scott Blood
Principal Consultant
Quality and Regulatory Services
151 Gleasondale Road
Stow, Massachusetts 01775

Re: K222912
Trade/Device Name: clTrac
Regulation Number: 21 CFR 890.5900
Regulation Name: Power Traction Equipment
Regulatory Class: Class II
Product Code: ITH
Dated: April 17, 2023
Received: April 20, 2023

Dear Scott Blood:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Lauren E. Woodard -S

for Amber Ballard, PhD
Assistant Director
DHT5B: Division of Neuromodulation
and Physical Medicine Devices
OHT5: Office of Neurological
and Physical Medicine Devices
Office of Product Evaluation and Quality
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K222912

Device Name
clTrac

Indications for Use *(Describe)*
clTrac is intended to provide relief for the management of pain and symptoms from a variety of pressures on muscular or skeletal structures. clTrac 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.

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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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
Fax: +49-731-9761-118
E-mail: u.killet@zimmer.de

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.