**DEPARTMENT OF HEALTH & HUMAN SERVICES** Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

October 16, 2015

Enraf-Nonius B.V.
% Mark Job
Responsible Third Party Official
Regulatory Technology Services, LLC
1394 25th Street, NW
Buffalo, Minnesota 55313

Re: K151640
Trade/Device Name: Eltrac 471
Regulation Number: 21 CFR 890.5900
Regulation Name: Power Traction Equipment
Regulatory Class: Class II
Product Code: ITH
Dated: September 16, 2015
Received: September 17, 2015

Dear Mark Job:

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 yours,

Carlos L. Pena -S

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)*
K151640

Device Name
Eltrac 471

Indications for Use *(Describe)*
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 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

## ELTRAC 471 Traction Device

1. **Date Prepared:**
   2015-09-09

2. **Owner:**
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4. **Trade name:**

| | |
|---|---|
| Trade name: | ELTRAC 471 |
| Common/Usual Name: | Traction Device |
| Classification Name: | 890.5900 Powered traction equipment |
| Product code: | ITH |

5. **Predicate device:**
   The Triton/Tru-Trac/TX/Triton DTS Traction devices provide traction and mobilization of skeletal structures and skeletal muscles. They were cleared for marketing in K053223 on February 24th, 2006, under Product Code ITH

6. **Device Description:**
   The Eltrac 471 traction device applies forces to the spine to alleviate pain caused by a variety of pressure on muscular or skeletal structures. It exerts defined forces on the human body to alleviate pain and utilizes computer technology for programming of different kinds of traction.

   This device is intended for use by professional users only, such as qualified personnel in physiotherapy, rehabilitation and adjacent areas. The device is designed with a plastic housing that holds the motor and has a full color touch screen interface on which the professional user can enter various parameters by touch. The forces from the motor are transferred to the patient by cords and connected accessories. Sequential programming is possible for programming combinations of traction which can be stored as favorites for later use.

The device has an on/off switch to power a medical power supply for 100-240V ~ 50/60Hz, and consumes a maximum of 50VA. The device has been designed for the standard US electric power sources and has a 100-240 VAC 50/60 Hz power supply.

To protect the patient from potential hazards, multiple mitigations are designed into the hardware and software. There are electronic safeguards of force and mechanical safety for maximum force limitation. Additional hardware mitigations are applied to protect the patient from excessive force. If no software is running, or if no patient stop is connected, the hardware is designed to lower the force. The patient stop must be held by the patient during therapy. The patient can press it to stop therapy immediately. If it is pressed, the force will lower to release the patient from the device. The patient stop is controlled in the hardware, and any software will be overruled if it is pressed. A remote control can be used as an option for decreasing the force delivered to the patient during treatment. As a safety feature, the remote control cannot increase the force.

7. **Intended Use:**
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 syndrome, acute facet problems, radicular pain, prolapsed discs, spinal root impingement, hypomobility, degenerative joint disease, facet syndrome, compression fractures, joint pain, and discogenic pain.

8. **Summary of Technological Characteristics of the Eltrac 471 compared to predicate device:**
The intended uses of the Eltrac 471 and the predicate device are essentially still the same even though their indications for use statements have slightly different wording.

The technological characteristics of the Eltrac 471 and the predicate device are largely the same.

Both devices have an electrical input of 100-240V, 50/60Hz. Both devices employ software with touch-screen control to adjust settings, store treatment protocols, and provide reference information. Both devices utilize a software controlled motor to deliver force via a cord and accessories to apply traction to the patient.

Both devices are designed with safety/warning features so that cervical traction treatment decisions are made with care. In addition, treatment times

are limited and the patient is able to stop the treatment at any time with a switch.

The Eltrac 471 contains a subset of the traction body positions that the predicate device allows (i.e., the Eltrac 471 does not add anything new or more in that regard). The Eltrac 471 allows for only Lumbar (Face up) or Cervical (Lying) traction, whereas the predicate device allows Lumbar (Face up), Lumbar (Face down) or Cervical (Lying). This difference with the Eltrac only means that the professional user cannot treat patients for face down lumbar traction. This difference is not raising any new technological characteristic with the Eltrac 471.

There are negligible differences between the Eltrac 471 and the predicate device in regards to traction force and base force. The Eltrac 471 and the predicate device are substantially equivalent in this regard.

The difference in the maximum treatment time between the Eltrac 471 to the predicate device also does not add any new or additional risks. The Eltrac 471 allows for 150 minutes total treatment time, whereas the predicate device allows 165 minutes. (For both devices, the normal treatment time will generally be around 20-30 minutes.) Further, total allowable treatment time can always be extended by the professional user using either the Eltrac 471 or the predicate device, as both allow the professional user to restart or extend a treatment time. Therefore, the difference in maximum treatment time between the Eltrac 471 and the predicate device does not add any new or additional risks to the predicate device (i.e., the Eltrac 471 is substantially equivalent to the predicate device in this regard).

The Eltrac 471 is also substantially equivalent to the predicate device in regards to force speed. The Eltrac 471 has a defined force speed, whereas the predicate device has an unknown force speed because of variables that influence the force speed, which are mostly the level of force and the elasticity of the patient. The predicate device's level of force varies because the higher the force, the more power is dissipated into heat, which results in a lower force speed (N/s). The elasticity of the patient is also a variable, through which a force set point is reached faster (i.e., higher force speed) when a patient has low elasticity compared to a patient with higher elasticity. The Eltrac 471 has a controlled force speed which is independent of the patient's elasticity; this aspect would not render the Eltrac 471 to not be substantially equivalent to the predicate device.

The Traction Force Hold Time and Traction Base Force Rest Time appear to be different, but the professional user is responsible for setting acceptable values for both the Eltrac 471 and the predicate device. When a very long Hold Time or Rest Time is set, it will become a Static Force. Both traction types are valid and can be used safely in both devices.

The differences between the Eltrac 471 and the identified predicate do not negatively affect the safety and effectiveness of the Eltrac 471 for the proposed indications for use, and most importantly, the Eltrac 471 is substantially equivalent to the predicate device despite these differences.

**9. Non-clinical Performance:**

Verification and validation tests were executed by Enraf-Nonius, B.V. to establish the performance and functionality of ELTRAC 471. Several standards were utilized:

- ISO 14971 — Medical Devices – Application of risk management to medical devices
- IEC 60601-1 — Medical electrical equipment – Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-2 — Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic disturbances – Requirements and tests
- IEC 62304 — Medical Device Software – Software Life Cycle Process

**10. Clinical Performance:**

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

**11. Conclusion:**

The Eltrac 471 traction device has the same intended use and technological characteristics as the predicate device. The testing done according to the company's internal standards and industry technical standards demonstrate that the Eltrac 471 meets the requirements for electrical and EMC safety, and meets the same safety and efficacy level of the predicate device.

In conclusion, the Eltrac 471 traction device is substantially equivalent to the Triton/Tru-Trac/TX/Triton DTS traction device (K053223).

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