February 22, 2024

Ergo-Flex Technologies, LLC
% M. Heinrich
President
Texas Applied Biomedical Services
12101 Cullen Blve. Suite A
Houston, Texas 77047

Re: K214037
Trade/Device Name: Ergo-Flex Technologies Back on Trac (BOTGEN1) and Cervi-Trac
Regulation Number: 21 CFR 890.5900
Regulation Name: Power traction equipment
Regulatory Class: Class II
Product Code: ITH, ILZ, IRT, IRO
Dated: February 7, 2024
Received: February 7, 2024

Dear M. Heinrich:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Amber T. Ballard -S

Amber Ballard, PhD
Assistant Director
DHT5B: Division of Neuromodulation
and Rehabilitation 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):* K214037

Device Name: Ergo-Flex Technologies Back on Trac (BOTGEN1) and Cervi-Trac

Indications for Use *(Describe)*

The Back on Trac (BOTGEN1) and Cervi-Trac Systems are intended for use in professional healthcare facilities, to relieve pressures on structures that may be causing pain of skeletal or muscular origin (cervical, thoracic, lumbar, hip, shoulder).

Back on Trac

The Back on Trac (BOTGEN1) is intended for use to relieve pressures on structures that may be causing pain of skeletal or muscular origin (cervical, thoracic, lumbar, hip, shoulder)". The device may be used to manage and reduce pain associated with the following conditions:

- facet syndrome,
- herniated disc,
- protruding disc,
- extruded disc,
- sciatica,
- spondylosis (degenerative disc disease & facet syndrome),
- joint pain.

Vibration and heat are available options that can be utilized with the Back on Trac (BOTGEN1) at the discretion of the healthcare professional. When activated, the vibration mode can provide muscle relaxation and temporary relief of minor aches and pains. The heat mode, when activated, can provide temporary relief of minor aches and pains. The local warmth temporarily stimulates local blood circulation in your lower back.

Cervi-Trac

The Cervi-Trac is intended for use as an accessory to the Back on Trac (BOTGEN1) to relieve pressures on structures that may be causing pain of skeletal or muscular origin. The Cervi-Trac accessory focuses specifically on the cervical region.

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.

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510K Summary

1. GENERAL INFORMATION

Date Prepared: **February 22, 2024**
Device Generic Name: Power Traction Equipment

Trade Name: Ergo-Flex Technologies Back on Trac (BOTGEN1) and Cervi-Trac

Device Classification: Class II, Performance Standards
21CFR Part 890.5900 - Power Traction Equipment

Product Code: ITH
Additional Product Codes: ILZ, IRT, IRO

Applicant Name / Address:
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510(k) Number: K214037

2. Device Description

The Ergo-Flex Technologies Systems that are the subject of this premarket notification are prescription use only and are intended for use by licensed, qualified healthcare professionals, such as physicians, chiropractors, physical therapists, etc.

Ergo-Flex Back on Trac System:

The Back on Trac (BOTGEN1) is intended for use in professional healthcare facilities, to relieve pressures on structures that may be causing pain of skeletal or muscular origin (cervical, thoracic, lumbar, hip, shoulder). The device may be used to \ manage and reduce pain associated with the following conditions: facet syndrome, herniated disc, protruding disc, extruded disc, sciatica, spondylosis (degenerative disc disease & facet syndrome), and joint pain.

Vibration and heat are available options that can be utilized with the Back on Trac (BOTGEN1) at the discretion of the healthcare professional. When activated, the vibration mode can provide muscle relaxation and temporary relief of minor aches and pains. The heat mode, when activated, can provide temporary relief of minor aches and pains. The local warmth temporarily stimulates local blood circulation in your lower back.

The (BOTGEN1) is comprised of a reclinable therapeutic cushioned chair with back support portion and a second lower back, upper and lower leg support section that is movable in an axial direction with respect to the back support section and is also arcuately movable about a pivot axis that is perpendicular to the axial direction. The chair includes remotely controlled linear actuators to control the relative movement of the different sections of the device.

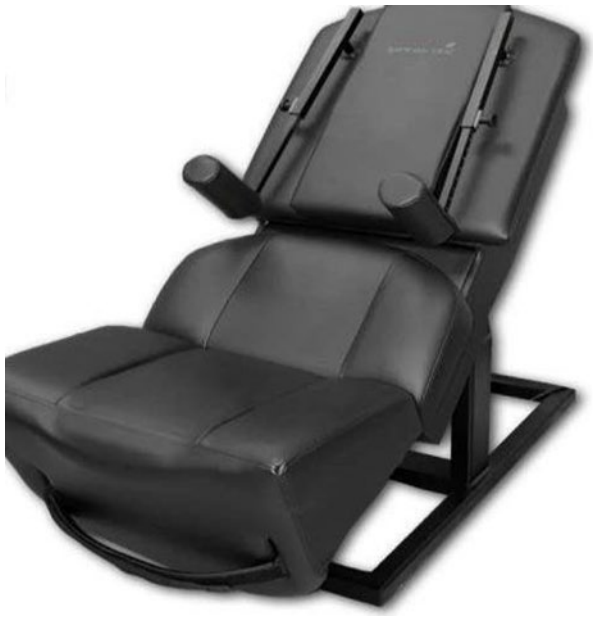

Figure 1. Ergo-Flex Back on Trac (BOTGEN1)

Ergo-Flex Cervi-Trac:

The Cervi-Trac (CT), as shown in Figure 2, is an accessory to the Back on Trac (BOTGEN1) that focuses specifically on the cervical region. The patient is not restrained by the Back on Trac arm bolsters, therefore lumbar traction is not activated by the Cervi-Trac during this therapy.

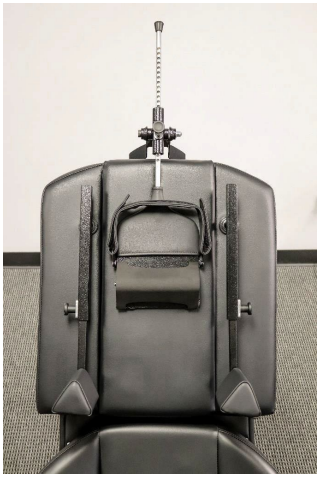

Figure 2. Cervi-Trac (attached to Back on Trac)

3. Indications for Use

The Back on Trac (BOTGEN1) and Cervi-Trac Systems are intended for use in professional healthcare facilities, to relieve pressures on structures that may be causing pain of skeletal or muscular origin (cervical, thoracic, lumbar, hip, shoulder).

Back on Trac (BOTGEN1)
The Back on Trac (BOTGEN1) is intended for use to relieve pressures on structures that may be causing pain of skeletal or muscular origin (cervical, thoracic, lumbar, hip, shoulder)". The device may be used to manage and reduce pain associated with the following conditions:

- facet syndrome,
- herniated disc,
- protruding disc,
- extruded disc,
- sciatica,
- spondylosis (degenerative disc disease & facet syndrome),

- joint pain.

Vibration and heat are available options that can be utilized with the Back on Trac (BOTGEN1) at the discretion of the healthcare professional. When activated, the vibration mode can provide muscle relaxation and temporary relief of minor aches and pains. The heat mode, when activated, can provide temporary relief of minor aches and pains. The local warmth temporarily stimulates local blood circulation in your lower back.

Cervi-Trac
The Cervi-Trac is intended for use as an accessory to the Back on Trac (BOTGEN1) to relieve pressures on structures that may be causing pain of skeletal or muscular origin. The Cervi-Trac accessory focuses specifically on the cervical region.

4. Predicate Devices

The Back on Trac (BOTGEN1) and Cervi-Trac Systems are substantially equivalent to other power traction devices that have been previously cleared by the FDA via the 510K process.

510(k) Number	Predicate Device Name	Manufacturer
K053223	Triton/Tru-Trac/TX/ Triton DTS Traction	Chattanooga Group

5. Summary of the Technical Characteristics of the Subject Device to the Predicate Device.

The Indications for Use Statement listed for the Back on Trac (BOTGEN1) and Cervi-Trac accessory are similar to the indications for use of the predicate device. The technical characteristics and operational parameters of the Back on Trac (BOTGEN1) and Cervi- Trac and the predicate devices are substantially equivalent. Table 1 shows a comparison of the primary technological characteristics and operational parameters of the Back on Trac (BOTGEN1) and Cervi-Trac to the referenced predicate devices.

Table 1.

Comparison of the IFU and Technical Specifications and Performance Characteristics of the Back on Trac (BOTGEN1) and Cervi-Trac to the Triton/Tru-Trac/TX/Triton DTS Traction

Parameter	Back on Trac (BOTGEN1) / Cervi-Trac	Triton/Tru-Trac/TX/ Triton DTS Traction	Similarities and Differences
K Number	K214037	K053223	N/A
Intended Use	Prescription use only	Prescription use only	Same
Environment	Professional healthcare facilities, clinics and/ or hospitals	Professional healthcare facilities, clinics and/ or hospitals	Same
Use	The Back on Trac (BOTGEN1) and Cervi- Trac Systems are intended for use in professional healthcare facilities, to relieve pressures on structures that may be causing pain of skeletal or muscular origin (cervical, thoracic, lumbar, hip, shoulder). Back on Trac (BOTGEN1) The Back on Trac is intended for use to relieve pressures on structures that may be causing	The Triton/ Tru-Trac/TX/Triton DTS Traction devices provide traction and mobilization of skeletal structures and skeletal muscles. The Triton/ Tru-Trac/TX/Triton DTS Traction devices provide a treatment in static, intermittent, progressive, regressive and cycling distraction forces to relieve pressures on structures that may be causing pain of skeletal or muscular	Similarities: The Back on Trac (BOTGEN1), Cervi-Trac and the predicate relieve pressures on structures that may be causing pain of skeletal or muscular origin (cervical, thoracic, lumbar, hip, shoulder).

	pain of skeletal or muscular origin (cervical, thoracic, lumbar, hip, shoulder)". The device may be used to manage and reduce pain associated with the following conditions: • facet syndrome, • herniated disc, • protruding disc, • extruded disc, • sciatica, • spondylosis (degenerative disc disease & facet syndrome), • joint pain. Vibration and heat are available options that can be utilized with the Back on Trac at the discretion of the healthcare professional. When activated, the vibration mode can provide muscle relaxation and temporary relief of minor aches and pains. The heat mode, when activated, can provide temporary relief of minor aches and pains. The local warmth temporarily stimulates local blood circulation in your lower back. <u>Cervi-Trac</u> The Cervi-Trac is intended for use as an accessory to the Back on Trac (BOTGEN1) to relieve pressures on structures that may be causing pain of skeletal or muscular origin. The Cervi-Trac accessory focuses specifically on the cervical region.	origin (cervical, thoracic, lumbar, hip, wrist, shoulder). Therapeutic distraction can be applied in a variety of programmable patterns, cycles and functions. The Triton/ Tru-Trac/ TX/ Triton DTS 'Traction devices with the optional EMG (a.k.a. sEMG) biofeedback feature 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 disc • Spinal root impingement • Degenerative joint disease • Facet syndrome • Compression fractures • Joint pain • Discogenic pain EMG (a.k.a. sEMG) • Determination of the activation magnitude and timing of muscles for: a) retraining of muscle activation b) coordination of muscle activation • Determination of the force produced by muscle for control and maintenance of muscle contractions. • Relaxation muscle training • Muscle re-education	Differences: The Back on Trac has optional Vibration and Heat modes. The Back on Trac does not include biofeedback option.
Treatment Areas	Cervical / Lumbar / Thoracic / Hip / Wrist / Shoulder	Cervical / Lumbar / Thoracic / Hip / Wrist / Shoulder	Same
Electrical Classification and Type	Class II Type B	Not Publicly Available	UNK
Electrical Safety Consensus Standard	IEC 60601-1:2005	UL 60601-1:2003	Same
EMC Consensus Standard	IEC 60601-1-2	IEC 60601-1-2:2001	Same
Usability Consensus Standard	IEC 60601-1-6	Not Publicly Available	UNK
Biocompatibility	IEC 10993-5:2009	Not Publicly Available	UNK

Traction Mechanism	Electromechanical	Electromechanical	Same
Actuation Mechanism	Electromechanical	Not Publicly Available	UNK
Traction Force	Min and Max traction force: BOT = 0 – 91lbs. Cervi-Trac= 0 – 34.5 lbs.	Not Publicly Available	UNK
Operational Components	Software controlled actuator for traction and flexion	Software controlled traction	Same
Traction Speed	Continuous, Adjustable (~0.25″/second)	Not Publicly Available	UNK
Treatment Time	5 – 15 minutes	Not Publicly Available	Similar
Therapy Mode	Continuous	Not Publicly Available	UNK
Power Supply	110-120V (60Hz) 220-240V (50Hz)	Not Publicly Available	UNK
Battery Backup	Yes	N/A	Back on Trac has a battery backup should there be a power failure.
Environmental Conditions (Temperature, relative humidity, air pressure)	Work: +10□ to 40□ C, 30 to 75% non-condensing, 700-1060 hPa storage:+5 to 45* C, not exceeding 75% non-condensing, 700-1060 hPa transport:+10 to 45* C, 20 to 95% non-condensing, 700-1060 hPa	Not Publicly Available	UNK

6. Testing

Clinical Performance:
Not applicable. Clinical testing was not provided to demonstrate the substantial equivalence of the Back on Trac (BOTGEN1) and Cervi-Trac.

Non-Clinical Performance:
The Back on Trac (BOTGEN1) and Cervi-Trac devices undergo 100% performance testing and Quality Assurance inspection by Ergo-Flex Technologies in accordance with the Company's written standard operating procedures (SOP) prior to release to inventory. All Quality Assurance and performance test documentation is maintained in the Device History Record at the Corporate site as required by 21 CFR 820.184.

Performance testing on the Back on Trac (BOTGEN1) and Cervi-Trac Systems demonstrated the design, operational and functional parameters and safety features met the established specifications for each device and demonstrate performance substantial that is equivalent to the predicate device.

The Back on Trac (BOTGEN1) System has been evaluated and tested by independent certified testing facilities in conformance the following consensus standards:

FDA Recognition Number	Standard	Description
19-46	IEC 60601-1:2005 + A1:2012	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
19-8	IEC 60601-1-2:2015	Medical electrical equipment – Part 1-2: General requirements for safety – Collateral standard: Electromagnetic Compatibility
5-89	IEC 60601-1-6:2010 + A1:2013	Medical electrical equipment – Part1: General requirements for safety Collateral standard: Usability
5-40	ISO 14971:2007	Medical Devices – Application of Risk Management to Medical Devices
5-114	IEC 62366-1:2015	Medical Devices – Part 1: Application of usability engineering to medical devices
19-29	ANSI C63.27	ANSI for Evaluation of Wireless Coexistence
	IEC 10993:2017	Biocompatibility

7. Conclusions

By definition, a device is substantially equivalent to a predicate device when the device has the same intended use and the same technological characteristics as the previously cleared predicate device. Or the device may have the same intended use and different technological characteristics if they can be demonstrated that the device is substantially equivalent to the predicate device, and that the new device does not raise different questions regarding its safety and effectiveness as compared to the predicate device.

Pursuant to the testing and comparison to the predicate devices, the Ergo Flex Technologies, LLC Back on Trac (BOTGEN1) and Cervi-Trac devices have the same and/or equivalent intended uses, with similar technical, functional and performance characteristics as the predicate devices listed above.

The Back on Trac (BOTGEN1) and Cervi-Trac Systems perform as intended and do not raise any new safety or efficacy issues.