July 18, 2025

Excite Medical of Tampa Bay, LLC
℅ Jon Werner
QA / RA Consultant
Cofactor Technologies, Inc.
2002 Blind Pond Ave
Lutz, Florida 33549

Re: K243775
Trade/Device Name: True Non-Surgical Spinal Decompression System (DRX9000-SL)
Regulation Number: 21 CFR 890.5900
Regulation Name: Power Traction Equipment
Regulatory Class: Class II
Product Code: ITH
Dated: June 27, 2025
Received: June 27, 2025

Dear Jon Werner:

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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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
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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K243775

Device Name
DRX9000-SL True Non-Surgical Spinal Decompression System

Indications for Use *(Describe)*
The DRX9000-SL True Non-Surgical Spinal Decompression System provides a primary treatment modality for the management of pain and disability for patients suffering with incapacitating low back pain and sciatica. It is designed to apply spinal decompressive forces to compressive and degenerative injuries of the spine. It has been found to provide relief of pain and symptoms associated with herniated discs, bulging or protruding intervertebral discs, degenerative disc disease, posterior facet syndrome and sciatica.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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510(k) Summary

In accordance with the requirements of the Safe Medical Device Act of 1990 and 21 CFR 807.92, Excite Medical of Tampa Bay is hereby submitting the 510(k) Summary of Safety and Effectiveness for 510(k) Number K243775.

Date Prepared: 25 June 2025

A. SUBMITTER

Excite Medical of Tampa Bay, LLC
4710 Eisenhower Blvd N Suite A-12
Tampa, FL 33634
Establishment Registration Number: 3008816697

Company Contact:

Saleem Musallam
President
Tel: (813) 210-1000
sm@excitemedical.com

B. DEVICE NAME

Proprietary Name:	DRX9000-SL True Non-Surgical Spinal Decompression System
Model Numbers:	DRX9000-SL True Non-Surgical Spinal Decompression System Upper (Chest) Harnesses (E-UBH-XS/S/M/L/XL) Lower (Pelvic) Harnesses (E-PH-XS/S/M/L/XL) 51-0007 Head Pillow 51-0008 Knee Pillow
Common Name:	Equipment, Traction, Powered
Classification Names:	Powered Traction Equipment
Regulation Number:	21 CFR Part 890.5900
Classification:	Class II
Product Code:	ITH

C. PREDICATE / LEGALLY MARKETED DEVICES

Device Name:	DRX9000 True Non-Surgical Spinal Decompression System
Company Name:	Axiom Worldwide, Inc.
510(k) #:	K060735

D. DEVICE DESCRIPTION

The DRX9000-SL True Non-Surgical Spinal Decompression System provides accurately controlled tensions designed to relax and confuse paraspinal muscles and allow distractive forces to decompress intervertebral spinal disc space. The user interface provided by the treatment computer constantly updates a servo-amplifier controlling a servo-motor to immediately and safely apply forces as determined by qualified healthcare personnel. Load-cell feedback is utilized to further verify and adjust tensile forces, allowing for variations in patient posture and outside forces such that continuous and smooth tension is experienced by the patient.

An upper chest harness and a lower pelvic harness are used to help distribute the applied forces evenly. Once in place, the patient is slowly reclined to a horizontal position. Following the physician's orders, the therapist localizes the pain, makes any adjustments and directs the treatment to the proper area. The DRX9000-SL True Non-Surgical Spinal Decompression System helps to mobilize the troubled disc segment without introducing further damage to the spine.

The patient safety switch is held by the patient who at any time and for any reason may quickly pause any tensile forces. The patient safety switch is monitored and executed by two redundant systems, which will gradually reduce the tension to zero to stop the treatment and after a 5 second delay directly disable the treatment motor.

The emergency stop button is accessible to the operator who at any time and for any reason may quickly pause any tensile forces. The emergency stop button is monitored and executed by two redundant systems, which will gradually reduce the tension to zero to stop the treatment and after a 5 second delay directly disable the treatment motor.

Integral to effective spinal decompression and included in the device are continuous load-cell tensile feedback into the treatment computer, dedicated and matched servo-amplifier and servo-motor, smoothly modulated cyclic tension application (high and low tension plateaus transitioned into via non-linear tension change), two segment (upper and lower) textile patient harness, patient safety switch, and free-floating lower body mattress. The free-floating lower body mattress allows the interdiscal segments of the lumbar spine to decompress at their own rate. As tension is cycled, the lower body can extend independent of the upper body which is held in place via an upper body textile patient harness. The treatment bed and textile harness allow the patient to relax completely and require no conscious exertion on the part of the patient. Total patient relaxation encourages paraspinal muscle relaxation from both a physical and psychological standpoint and is a key to spinal decompression.

E. INTENDED USE / INDICATIONS FOR USE

The DRX9000-SL True Non-Surgical Spinal Decompression System provides a primary treatment modality for the management of pain and disability for patients suffering with incapacitating low back pain and sciatica. It is designed to apply spinal decompressive forces to compressive and degenerative injuries of the spine. It has been found to provide relief of pain and symptoms associated with herniated discs, bulging or protruding intervertebral discs, degenerative disc disease, posterior facet syndrome and sciatica.

F. COMPARISON OF THE TECHNOLOGICAL CHARACTERISTICS

The DRX9000-SL True Non-Surgical Spinal Decompression System indications for use is the same as the predicate device. The technical characteristics and operational parameters of the DRX9000-SL True Non-Surgical Spinal Decompression System are substantially equivalent. The table below shows a comparison of the primary technological characteristics and operational parameters of the DRX9000-SL True Non-Surgical Spinal Decompression System to the referenced predicate device.

	Subject Device (K243775) DRX9000-SL True Non-Surgical Spinal Decompression System	**Predicate Device (K060735) DRX9000 True Non-Surgical Spinal Decompression System**
Intended Use	Prescription use only	Prescription use only
Environment	Professional healthcare facilities, clinics and / or hospitals	Professional healthcare facilities, clinics and / or hospitals
Indications for Use	The DRX9000-SL True Non-Surgical Spinal Decompression System provides a primary treatment modality for the management of pain and disability for patients suffering with incapacitating low back pain and sciatica. It is designed to apply spinal decompressive forces to compressive and degenerative injuries of the spine. It has been found to provide relief of pain and symptoms associated with herniated discs, bulging or protruding intervertebral discs, degenerative disc disease, posterior facet syndrome and sciatica.	The DRX9000 True Non-Surgical Spinal Decompression System provides a primary treatment modality for the management of pain and disability for patients suffering with incapacitating low back pain and sciatica. It is designed to apply spinal decompressive forces to compressive and degenerative injuries of the spine. It has been found to provide relief of pain and symptoms associated with herniated discs, bulging or protruding intervertebral discs, degenerative disc disease, posterior facet syndrome and sciatica.
Treatment Areas	Lumbar	Lumbar
Electrical Classification and Type	Class I Type BF	Not publicly available
Electrical Safety Consensus Standard	IEC 60601-1:2005 + A1:2012 + A2:2020	Not publicly available

	Subject Device (K243775) DRX9000-SL True Non-Surgical Spinal Decompression System	**Predicate Device (K060735) DRX9000 True Non-Surgical Spinal Decompression System**
EMC Consensus Standard	IEC 60601-1-2:2014 + A1:2020	Not publicly available
Usability Consensus Standard	IEC 60601-1-6:2010 + A1:2013 + A2:2020	Not publicly available
Biocompatibility	In accordance with ISO 10993-1:2018 and FDA# G95-1	Not publicly available
Traction Mechanism	Electromechanical	Electromechanical
Operational Components	Software controlled servo amplifier and servo motor for traction and flexion	Not publicly available
Traction Force	Traction limits can be varied between 0 – 150lbs pull	Traction limits can be varied between 0 – 150lbs pull
Traction Speed	Continuous, Adjustable	Continuous, Adjustable
Treatment Time	Up to 30 minutes	Up to 30 minutes
Therapy Mode	Continuous	Continuous
Power Supply	100-120VAC / 220-230 VAC, 50/60 Hz	Not publicly available
Battery Backup	Yes	Not publicly available
Environmental Conditions	Storage / Operation +10 to +40 Celsius 30% to 75% non-condensing 700 to 1060 hPa	Not publicly available
Materials	Mattress / Pillow Surfaces: REM114 ADF Remington	Not publicly available

G. SUMMARY OF NON-CLINICAL TESTING

Non-clinical tests were performed on the DRX9000-SL True Non-Surgical Spinal Decompression System in order to verify and validate the design and to assure conformance with the following voluntary design standards in connection with electrical safety, electromagnetic compatibility, usability, risk management, biocompatibility and software.

Type	Description
Electrical safety	• IEC 60601-1:2005 + A1:2012 + A2:2020 [19-49] Medical electrical equipment – Part 1: General requirements for basic safety and essential performance
Electromagnetic compatibility	• IEC 60601-1-2:2014 + A1:2020 [19-36] Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic disturbances – Requirements and tests • IEC TR 60601-4-2:2016 [19-19] Medical electrical equipment – Part 4-2: Guidance and interpretation – Electromagnetic immunity: performance of medical electrical equipment and medical electrical systems
Risk management	• ISO 14971:2019 [5-125] Medical devices – Application of risk management to medical devices
Biocompatibility	• ISO 10993-1:2018 [5-258] Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process
Software	• IEC 62304:2006 + A1:2015 [13-79] Medical device software – Software life cycle processes

H. SUMMARY OF CLINICAL TESTING

Clinical testing is not required for this submission. The non-clinical performance testing described above is sufficient to support substantial equivalence of the subject device to the predicate device.

I. CONCLUSION

The DRX9000-SL True Non-Surgical Spinal Decompression System has the same intended use, indications for use, treatment location, conditions of use, and fundamental scientific technology as the predicate device. The conclusions drawn from the nonclinical performance testing (discussed above) demonstrate that the device raises no new issues of safety or effectiveness and that the DRX9000-SL True Non-Surgical Spinal Decompression System is therefore substantially equivalent to the DRX9000 True Non-Surgical Spinal Decompression System cleared by K060735.