May 18, 2018

Providence Medical Technology, Inc.
Edward Liou
Chief Operating Officer
3857 Hopyard Rd.
Suite 300
Pleasanton, California 94588

Re: K180876
Trade/Device Name: DTRAX Spinal System
Regulation Number: 21 CFR 888.1100
Regulation Name: Arthroscope
Regulatory Class: Class II
Product Code: HRX
Dated: April 2, 2018
Received: April 3, 2018

Dear Edward Liou:

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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Jennifer R. Stevenson -S3

For Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K180876

Device Name
DTRAX® Spinal System

Indications for Use *(Describe)*
DTRAX Spinal System is a set of instruments indicated to be used to perform posterior cervical fusion in patients with cervical degenerative disc disease.

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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Section 6. 510(k) Summary

510(k) Owner:	Providence Medical Technology, Inc. 3875 Hopyard Rd., Suite 300 Pleasanton, CA 94588 T: 415-923-9376 F: 415-923-9377
Contact Person:	Edward Liou Email: ed@providencemt.com T: 415-754-8593
Date Summary Prepared:	May 16th, 2018
Trade Name:	DTRAX® Spinal System
Common Name:	Arthroscopic Accessories
Device Classification Regulation:	21 CFR 888.1100
Device Product Code & Panel:	HRX Orthopaedic and Rehabilitation Devices Panel
Primary Predicate Device:	Vertos Medical, Inc. Vertos Medical mild® Device Kit (K093062)
Reference Devices:	Dyonics, Inc. The Arthrofile (K812506) Transcorp, Inc. Transcorp Spinal Access System (K113352) Aesculap, Inc. Hi Line XS disposable Rosen Burr III (Class I exempt) Medtronic Cervical FacetLift ID/S Instruments (Class I exempt)

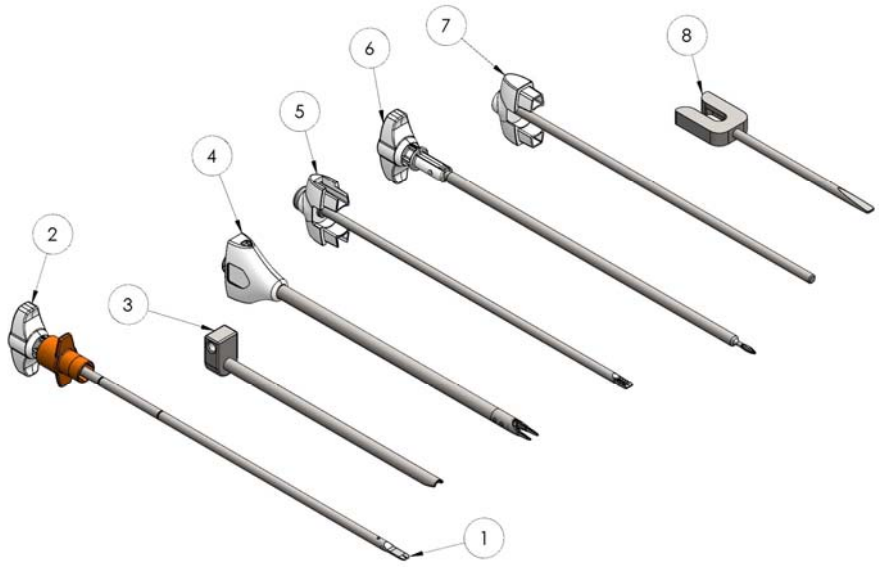
Device Information

A. Device Description

The DTRAX® Spinal System is a set of surgical instruments indicated for performing posterior cervical fusion. The instruments will be supplied sterile and single use only. The system consists of a facet joint access tool, lateral mass decortication trephine, mallet, cannula, decortication rasp, decortication burr, and tamp. In combination, these instruments allow the user to access the posterior cervical spine to perform posterior cervical fusion by decortication of bone surfaces, including the posterior lateral mass and facet joints, combined with application of autograft or allograft.

DTRAX® Spinal System
Catalog# DX-22-100

Item Number	Part Number	Description
1	PT-01-100	Access Chisel
2	PD-34-100	Access Chisel Handle
3	PD-05-200	Decortication Trephine
4	PD-04-000	Guide Tube
5	PD-02-101	Decortication Rasp
6	PD-02-300	Decortication Burr
7	PD-12-000	Bone Graft Tamp
8	PD-05-004	Fork Mallet



B. Indications for Use

DTRAX® Spinal System is a set of instruments indicated to be used to perform posterior cervical fusion in patients with cervical degenerative disc disease.

C. Summary of Technological Characteristics

The fundamental operational principles, surgical approach, design, materials, and performance of the DTRAX® Spinal System and the predicate device are essentially the same. Therefore, the technological characteristics of the DTRAX® Spinal System do not raise any new safety and effectiveness questions not addressed in the predicate device.

D. Summary of Performance Testing

Non-clinical testing has demonstrated the DTRAX® Spinal System meets the performance requirements to safely distribute and use in accordance with the Indication for Use.

- Simulated use cadaveric testing demonstrated the instruments can be used to perform posterior cervical fusion in patients with cervical degenerative disc disease.
- The bench testing demonstrated the safety and efficacy of the instruments and the strength and integrity to resist impaction, insertion, removal, and rotational loads to perform the stated intend use.
- Additionally, the DTRAX® Spinal System demonstrated that it is in compliance with the following FDA consensus standards:
    - FDA Recognition Number 14-428: ISO 11137-1 First Edition 2006-04-15 Sterilization Of Health Care Products - Radiation - Part 1: Requirements For Development, Validation And Routine Control Of A Sterilization Process For Medical Devices [Including: Amendment 1 (2013)]
    - FDA Recognition Number 14-438: ISO 11137-2 Third Edition 2013-06-01 Sterilization Of Medical Devices - Microbiological Methods - Part 2: Tests Of Sterility Performed In The Definition, Validation And Maintenance Of A Sterilization Process
    - FDA Recognition Number 14-407: ISO 11737-1 Second Edition 2006-04-01 Sterilization of Medical Devices – Microbiological Methods – Part 1: Determination of a Population of Microorganisms on Products
    - FDA Recognition Number 14-287: ISO 11737-2: 2009/(R) 2014 Sterilization of medical devices – Microbiological methods – Part 2: Tests of Sterility Performed in the Definition, Validation and Maintenance of Sterilization Process.
    - FDA Recognition Number 14-457: ISO 11607-1:2006/(R)2010 Packaging For Terminally Sterilized Medical Devices - Part 1: Requirements For Materials, Sterile Barrier Systems And Packaging [Including: Amendment 1 (2014)]
    - FDA Recognition Number 14-458: ISO 11607-2:2006/(R)2010 Packaging for Terminally Sterilized Medical Devices – Part 2: Validation Requirements for Forming, Sealing and Assembly Processes [Including: Amendment 1 (2014)
    - FDA Recognition Number 2-156: ANSI AAMI ISO10993-1:2009/(R)2013 Biological Evaluation Of Medical Devices - Part 1: Evaluation And Testing Within A Risk Management Process
    - FDA Recognition Number 8-344: ISO 7153-1 Second Edition 1991-04-01 Surgical Instruments -- Metallic Materials -- Part 1: Stainless Steel [Including: Amendment 1 (1999)]
    - FDA Recognition Number 8-343: ASTM F899-12b Standard Specification for Wrought Stainless Steels for Surgical Instruments

E. Basis of Substantial Equivalence

The DTRAX® Spinal System is substantially equivalent compared to the cleared primary predicate device, Vertos Medical, Inc., Vertos Medical Mild® Device Kit (K093062) and the reference devices, on the basis the devices have the same technological characteristics, similar design features, same materials and principles of operation. Performance data demonstrate that the DTRAX® Spinal System is as safe and effective as the predicate devices.