July 22, 2022

Rivarp Medical Private Limited
Sushma N.R
Manager - RA
No.34, Azeez Sait Industrial Town, 6th Mile,
Mysore Road,Nayandahalli.
Bangalore, Karnataka 560039
India

Re: K220486
Trade/Device Name: Kentrospine PSS Pedicle Screw System
Regulation Number: 21 CFR 888.3070
Regulation Name: Thoracolumbosacral Pedicle Screw System
Regulatory Class: Class II
Product Code: NKB
Dated: June 29, 2022
Received: July 6, 2022

Dear Sushma N.R:

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,

for

Colin O'Neill, M.B.E.
Assistant Director
DHT6B: Division of Spinal Devices
OHT6: Office of Orthopedic 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)*
K220486

Device Name
Kentrospine PSS Pedicle Screw System

Indications for Use *(Describe)*

The Kentrospine PSS Pedicle Screw System is intended for posterior, non-cervical fixation as an adjunct to fusion for skeletally mature patients for rigid fixation and stability with following indications: degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies); spondylolisthesis; trauma (i.e., fracture or dislocation); spinal stenosis; curvatures (i.e., scoliosis, kyphosis and/or lordosis); tumor; pseudarthritis; and/or failed previous fusion.

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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510(k) SUMMARY

Premarket Notification 510(k) Summary as required by Section 21 CFR 807.92

General Company Information as required by 807.92 (a)

Submitter's Name / Contact details:

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Contact Details:
Sushma N.R
Manager- Regulatory affairs
+91 80 2339 1136

Summary preparation date: 20th July 2022

Device name and classification:

Proprietary/ trade name:	Kentrospine PSS Pedicle Screw System
Common or Usual Name:	Pedicle Screw System
Classification Name:	Thoracolumbosacral Pedicle Screw System
Product Code(s):	NKB
Device Class:	Class II
Regulation Number:	21 CFR Section 888.3070
Review Panel:	Orthopedic

Variants/Types:

Kentrospine PSS Pedicle Screw System consists of following components.

- PSS Monoaxial Pedicle Screw
- PSS Polyaxial Pedicle Screw
- PSS Locking Cap
- PSS Crosslink Connector
- PSS Rod

Identification of the predicate device:

The identified primary predicate device within this submission is as follows: CD HORIZON® Spinal System (K091442) manufactured by Medtronic Sofamor Danek USA, dated July 15 2009.
The design features, material and indications for use of the Kentrospine PSS Pedicle Screw System are substantially equivalent to the predicate CD HORIZON® Spinal System.

Device Description:

The purpose of this Traditional 510(k) submission is to obtain market clearance for the Kentrospine PSS Pedicle Screw System. The Kentrospine PSS Pedicle Screw System is a top-loading multiple component, posterior spinal fixation system which consists of PSS Pedicle Screws (Monoaxial, polyaxial), PSS Rods, PSS Locking Cap, and a PSS Crosslink Connectors.

The Kentrospine PSS Pedicle Screw System will allow surgeons to build a spinal implant construct to stabilize and promote spinal fusion. Kentrospine PSS Pedicle Screw System components are supplied non-sterile, single use and are made from medical grade, biocompatible Titanium alloy (Ti6Al4V ELI) conforming to ASTM F136-13(2021)- Standard Specification for Wrought Titanium-6Aluminum-4Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications. Various sizes of these implants are available.

The PSS Pedicle Screws are available in diameters from Ø4.50mm to Ø7.00mm and in lengths of 25mm to 55mm. PSS Rods are straight, made from titanium and available in Ø5.50mm diameter with length from 45mm, 55mm, 65mm, 75mm, 85mm, 100mm, 125mm, 150mm, 200mm, 250mm, 300mm, 350mm, 450mm and 500mm.

Specialized instruments are available for the application and removal of the Kentrospine PSS Pedicle Screw System. The instruments are made from SAE 316L stainless steel which is complied with ASTM F899 – 20 Standard Specification for Wrought Stainless Steels for Surgical Instruments.

Indications for use:

The Kentrospine PSS Pedicle Screw System is intended for posterior, non-cervical fixation as an adjunct to fusion for skeletally mature patients for rigid fixation and stability with following indications: Degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies); Spondylolisthesis; Trauma (i.e., fracture or dislocation); Spinal stenosis; Curvatures (i.e., scoliosis, kyphosis and/or lordosis); Tumor; Pseudarthritis; and/or failed previous fusion.

Comparison to Technological Characteristics:

The Kentrospine PSS Pedicle Screw System is equivalent to the predicate device with respect to intended use, device design and material. All the necessary performance test to determine the mechanical characteristics have been performed on the Kentrospine PSS Pedicle Screw System

Performance data:
1.Non-clinical Performance:

The following tests have been conducted on the Kentrospine PSS Pedicle Screw System and the device performance has been demonstrated against following applicable standards,

1. Static compression bending testing (ASTM F 1717-21)
2. Static Torsional Testing (ASTM F 1717-21)
3. Static Tension bending Testing (ASTM F 1717-21)
4. Fatigue Compression testing (ASTM F 1717-21)

The results of this non-clinical testing shows that the strength and performance of the Kentrospine PSS Pedicle Screw System is sufficient for its intended use and is substantially equivalent to legally marketed predicate devices.

Following are the applicable material standards considered for Kentrospine PSS Pedicle Screw System:
1. ASTM F136-13(2021)-Standard Specification for Wrought Titanium-6Aluminum-4Vanadium ELI (Extra Low Interstitial) Alloy (Ti6Al4V ELI) for Surgical Implant Applications.
2. ASTM F899 – 20 Standard Specification for Wrought Stainless Steels for Surgical Instruments.

2. Clinical Performance Data/Information:

No clinical studies were performed.

Conclusion:

The Kentrospine PSS Pedicle Screw System is equivalent to the identified primary predicate device. From the data available we can justify that the Kentrospine PSS Pedicle Screw System has the same indications for use and similar technological characteristics as the legally marketed predicate device. Hence Kentrospine PSS Pedicle Screw System can be considered substantially equivalent to the predicate.