



September 27, 2026

Rivarp Medical Pvt., Ltd.
Sushma N.R
Manager-Regulatory Affairs
34, Azeez Sait Industrial Town, 6th Mile, Mysore Rd.,
Nayandahalli
Bangalore, Karnataka 560039
India

Re: K252139

Trade/Device Name: Kentrospine Viktr-MIS® Pedicle screw system
Regulation Number: 21 CFR 888.3070
Regulation Name: Thoracolumbosacral pedicle screw system
Regulatory Class: Class II
Product Code: NKB
Dated: June 30, 2025
Received: July 8, 2025

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 (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.

Your device is also subject to, among other requirements, the Quality Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485

clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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,

COLIN
O'NEILL -S 

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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.

K252139

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Please provide the device trade name(s).

?

Kentrospine Viktr-MIS® Pedicle screw system

Please provide your Indications for Use below.

?

The Kentrospine Viktr-MIS® Pedicle screw system is intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of acute and chronic instabilities or deformities of the thoracic, lumbar and sacral spine.

The Kentrospine Viktr-MIS® 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; Pseudarthrosis; and/or failed previous fusion.

The Kentrospine Viktr-MIS® Pedicle screw system can be used in an open approach and a percutaneous approach with Kentrospine Viktr-MIS® Pedicle screw system instruments.

Please select the types of uses (select one or both, as applicable).

☒ Prescription Use (Part 21 CFR 801 Subpart D)

☐ Over-The-Counter Use (21 CFR 801 Subpart C)

?

Contact Details

[21 CFR 807.92\(a\)\(1\)](#)

Applicant Name	Rivarp Medical Pvt.Ltd.,
Applicant Address	34, Azeez Sait Industrial Town, 6th Mile, Mysore Road Nayandahalli, Bangalore -560039, INDIA Bangalore Karnataka 560039 India
Applicant Contact Telephone	+91 9663372092
Applicant Contact	Mrs. Sushma N.R
Applicant Contact Email	sushma.nr@rivarpmedical.com

Device Name

[21 CFR 807.92\(a\)\(2\)](#)

Device Trade Name	Kentrospine Viktr-MIS® Pedicle screw system
Common Name	Thoracolumbosacral pedicle screw system
Classification Name	Thoracolumbosacral Pedicle Screw System
Regulation Number	888.3070
Product Code(s)	NKB

Legally Marketed Predicate Devices

[21 CFR 807.92\(a\)\(3\)](#)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K183117	PathLoc-L MIS Spinal System	NKB

Device Description Summary

[21 CFR 807.92\(a\)\(4\)](#)

The Kentrospine Viktr-MIS® Pedicle screw system is a posterior spinal fixation system, helps in spinal stabilization and promotes spinal fusion and to be used along with compatible instruments. The Kentrospine Viktr-MIS® Pedicle screw system is intended for percutaneous approach with Kentrospine Viktr-MIS® instrumentation.

The Kentrospine Viktr-MIS® Pedicle screw system will allow surgeons to build a spinal implant construct to stabilize and promote spinal fusion. Kentrospine Viktr-MIS® Pedicle screw system implant components are supplied non-sterile and to be sterilized by end user, 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 Kentrospine Viktr-MIS® Pedicle screw instruments are made from SAE 316L stainless steel which is complies to ASTM F899 – 20 Standard Specification for Wrought Stainless Steels for Surgical Instruments.

The Kentrospine Viktr-MIS® Pedicle screw system is available in diameters from Ø5.50mm , Ø6.5mm, Ø7.2mm and Ø7.50mm and in lengths of 25mm to 50mm. Viktr-MIS Rods are available in either straight or pre-contoured (curved) forms and made from Titanium alloy (Ti6Al4V ELI) and available in Ø5.50mm diameter with length from 40mm to 200mm (with 5mm increment) and 225mm,250mm,275mm & 300mm.

The Kentrospine Viktr-MIS ® Pedicle screw system consists of following components.

- Viktr-MIS Polyaxial cannulated pedicle screw
- Viktr-MIS Polyaxial long tab cannulated pedicle screw
- Viktr-MIS locking cap (Single step)
- Viktr-MIS Rod (Straight & pre-contoured/curved rod)

Intended Use/Indications for Use

[21 CFR 807.92\(a\)\(5\)](#)

The Kentrospine Viktr-MIS® Pedicle screw system is intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of acute and chronic instabilities or deformities of the thoracic, lumbar and sacral spine.

The Kentrospine Viktr-MIS® 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; Pseudarthrosis; and/or failed previous fusion.

The Kentrospine Viktr-MIS® Pedicle screw system can be used in an open approach and a percutaneous approach with Kentrospine Viktr-MIS® Pedicle screw system instruments.

Indications for Use Comparison

[21 CFR 807.92\(a\)\(5\)](#)

Kentrospine Viktr-MIS® Pedicle screw system has the same indications for use as legally marketed predicate device . Furthermore, any minor changes in the subject devices do not raise different kinds of safety and effectiveness questions. Verification and validation data support the substantial equivalence of Kentrospine Viktr-MIS® Pedicle screw system to the legally marketed predicate device.

Technological Comparison

[21 CFR 807.92\(a\)\(6\)](#)

Kentrospine Viktr-MIS® Pedicle screw system is equivalent to the legally marketed predicate devices with respect to intended use, device design and the material. All the necessary performance test to determine the mechanical characteristics have been performed on the Kentrospine Viktr-MIS® Pedicle screw system.

The Kentrospine Viktr-MIS® Pedicle screw System has similar technological and performance characteristics as of the predicate PathLoc-L MIS Spinal System(K183117).

Non-Clinical and/or Clinical Tests Summary & Conclusions

[21 CFR 807.92\(b\)](#)

The performance testing for the Kentrospine Viktr-MIS® Pedicle screw system complies with the applicable guidance documents and FDA recognized consensus standards.

- Guidance for Industry and FDA Staff Spinal System 510(k)s Document issued on: May 3, 2004
- ASTM F1717-21- Standard Test Methods for Spinal Implant Constructs in a Vertebrectomy Model.

All performance testing protocols, results, and conclusions are included in this submission under – Performance Testing-Bench testing.

- ASTM F1798-24-Standard Test Method for Evaluating the Static and Fatigue Properties of Interconnection Mechanisms and Subassemblies Used in Spinal Arthrodesis Implants.

This premarket submission did not rely on the assessment of clinical performance data to demonstrate substantial equivalence.

The following tests have been conducted on the Kentrospine Viktr-MIS® 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 / Dynamic Compression testing (ASTM F 1717-21)
5. Axial Gripping Capacity Test (ASTM F1798-24)
6. Torsional Gripping Capacity Test (ASTM F1798-24)
7. Static Flexion-Extension Moment Test (ASTM F1798-24)
8. Dynamic Flexion-Extension Moment Test (ASTM F1798-24)

The results of this non-clinical testing shows that the strength and performance of the Kentrospine Viktr-MIS® 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 Viktr-MIS® 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.