May 15, 2026

Kyocera Medical Technologies Inc. (KMTI)
% Hannah Taggart
Engineer & Regulatory Specialist
Applied Technical Services (Empirical Technologies)
Contact Address

Re: K260989
Trade/Device Name: Varion Thoracolumbar Fixation System
Regulation Number: 21 CFR 888.3070
Regulation Name: Thoracolumbosacral Pedicle Screw System
Regulatory Class: Class II
Product Code: NKB, OLO
Dated: [NOTE: Use date of most recent supplement]
Received: March 27, 2026

Dear Hannah Taggart:

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 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.	K260989

Please provide the device trade name(s).

Varion Thoracolumbar Fixation System

Please provide your Indications for Use below.

The KMTI Varion Thoracolumbar Fixation System is intended for posterior, non-cervical fixation in skeletally mature patients as an adjunct to fusion for the 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.

When used for posterior non-cervical screw fixation in pediatric patients, the Varion Thoracolumbar Fixation System is indicated as an adjunct to fusion to treat adolescent idiopathic scoliosis. Additionally, the Varion Thoracolumbar Fixation System is intended to treat pediatric patients diagnosed with the following conditions: spondylolisthesis/spondylolysis, and fracture caused by tumor and/or trauma. Pediatric pedicle screw fixation is limited to a posterior approach and is intended to be used with autograft and/or allograft.

The KMTI Varion Navigated Instruments System is intended to be used during the preparation and placement of KMTI screws during spinal surgery to assist the surgeon in precisely locating anatomical structures in either open or minimally invasive procedures. The KMTI Varion Navigated Instruments System is specifically designed for use with the Medtronic® StealthStation™ System, which is indicated for any medical condition in which the use of stereotactic surgery may be appropriate, and where reference to a rigid anatomical structure, such as a vertebra, can be identified relative to a CT or MR based model, fluoroscopy images, or digitized landmarks for the anatomy.

Please select the types of uses (select one or both, as applicable).	☒ Prescription Use (21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

510(K) SUMMARY

Submitter's Name:	Kyocera Medical Technologies, Inc.
Submitter's Address:	1289 Byrn Mawr Avenue, Suite A Redlands CA, 92374
Submitter's Telephone:	909-557-2360
Contact Person:	Hannah Taggart, MS, RAC Applied Technical Services (Empirical Technologies) 1-719-4571152 htaggart@atslab.com
Date Summary was Prepared:	March 25, 2026
Trade or Proprietary Name:	Varion Thoracolumbar Fixation System
Device Classification Name:	Thoracolumbosacral Pedicle Screw System Steretoxic Instrument System
Classification & Regulation #:	Class II per 21 CFR §888.3070 21 CFR §882.4560
Product Code:	NKB, OLO
Classification Panel:	Orthopedic – Division of Spinal Devices (DHT6B)

DESCRIPTION OF THE DEVICE SUBJECT TO PREMARKET NOTIFICATION:

The Kyocera Medical Technologies, Inc. (KMTI) Varion Thoracolumbar Fixation System is an internal thoracolumbar spinal fixation system comprised of longitudinal rods, polyaxial screws, modular tulips, and cross-links. The implant screw shanks, set screws, and tulips are manufactured from Ti-6Al-4V ELI per ASTM F136. The implant rods are manufactured from either Ti-6Al-4V titanium alloy per ASTM F136 or Co-28Cr-6Mo per ASTM F1537. The Varion Thoracolumbar Fixation System is offered in various sizes and configurations to accommodate patient anatomical needs.

The KMTI Varion Thoracolumbar Fixation System may be used with instruments from the KMTI Varion Navigated Instruments System for navigated preparation and placement of the implants during spinal surgery. The KMTI Varion Navigated Instruments System includes probes, taps, and drivers manufactured from medical grade stainless steel and titanium alloy which are compatible with Medtronic® StealthStation™ S8 System.

INDICATIONS FOR USE

The KMTI Varion Thoracolumbar Fixation System is intended for posterior, non-cervical fixation in skeletally mature patients as an adjunct to fusion for the 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.

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TECHNOLOGICAL CHARACTERISTICS

The predicates included in this submission were selected based on the best practices described in the FDA Draft Guidance document The subject and predicate devices have nearly identical technological characteristics and the minor differences do not raise any new issues of safety and effectiveness. Specifically, the following characteristics are identical between the subject and predicates:

- Indications for Use
- Structure and Function
- Size and Styles
- Materials of manufacture
- Sterility
- Manufacturing and biocompatibility
- Mechanical Strength

Predicate Devices

510k Number	Trade Name	Manufacturer	Product Code	Predicate Type
K210539	CoreLink Medilne Fixation System	CoreLink, LLC	NKB	Primary
K201648	Safe Orthopeadics	Sterispine™ PS	NKB, KWQ	Additional
K223494	CD Horizon Spinal System	Medtronic	OLO, NKB, KWP, KWQ, HBE	Additional

There are no differences between the subject and predicate devices which raise questions for the safety and efficacy of the subject devices.

PERFORMANCE DATA

The Varion Thoracolumbar Fixation System has been tested in the following test modes:

- Static Compression Bending per ASTM F1717
- Dynamic Compression Bending per ASTM F1717
- Static Torsion per ASTM F1717
- Static Axial Grip per ASTM F1798
- Static Torsion Grip per ASTM F1798
- Static Tulip-Shank Disassociation per ASTM F1798

The Varion Navigated Instruments System has been evaluated through an engineering analysis with a geometric comparison and a functional assessment of mating arrays and instrument verification compared to the

Medtronic equivalent navigated instruments showing equivalent critical geometry. Based upon the equivalency in geometry, performance testing such as positional accuracy per ASTM F2554 was not required.

The results of this non-clinical testing and analysis show that the performance of the Varion Thoracolumbar Fixation System and Varion Navigated Instruments System is sufficient for its intended use and is substantially equivalent to legally marketed predicate devices.

CONCLUSION

The overall technology characteristics and mechanical performance data lead to the conclusion that the Varion Thoracolumbar Fixation System and Varion Navigated Instruments System are substantially equivalent to the predicate device.