July 15, 2026

Kyocera Medical Technologies, Inc.
% Hannah Taggart
Engineer & Regulatory Specialist
ATS Colorado Springs
4628 Northpark Dr.
Colorado Springs, Colorado 80918

Re: K261353
Trade/Device Name: Tesera-K Anterior Lumbar Interbody Fusion (ALIF) System; Tesera-K XL System; Lumbar Anchor System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: OVD, MAX
Dated: May 7, 2026
Received: May 7, 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,

BRENT SHOWALTER -S

Brent Showalter, Ph.D.
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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K261353

Device Name
Tesera-K Anterior Lumbar Interbody Fusion (ALIF) System
Tesera-K XL System
Lumbar Anchor System

Indications for Use *(Describe)*
The Kyocera Medical Technologies, Inc. (KMTI) Lumbar Anchor System is indicated for use with the KMTI Tesera-K Anterior Lumbar Interbody Fusion (ALIF) System and Tesera-K XL System.
The KMTI Tesera-K ALIF System is indicated for interbody fusion procedures in skeletally mature patients with degenerative disc disease (DDD) in the lumbar spine at one or two contiguous levels from L2 to S1. DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. These DDD patients may have up to Grade 1 spondylolisthesis or retrolisthesis at the involved level(s). KMTI Tesera-K ALIF System implants are to be used with autogenous bone graft. Patients should be skeletally mature and have at least six months of non-operative treatment.
Tesera-K SA ALIF cages are intended to be implanted from a direct anterior surgical approach only. Tesera-K SA ALIF cages are intended to be used with the coverplate and screws provided or with the KMTI Lumbar Anchor System. Tesera-K SA ALIF assemblies (cage, lumbar anchors, screws and coverplate) featuring one or more lumbar anchors are considered non-standalone and require supplemental fixation cleared by the FDA for use in the lumbosacral spine. The coverplate assembly is required to be used if any anchors are implanted.
Tesera-K SA ALIF cages are intended to be implanted from a direct anterior surgical approach only. Tesera-K SA ALIF cages are intended to be used with the coverplate and screws provided. Tesera-K SA ALIF assemblies (cage, screws, coverplate) that contain cages with lordotic angles less than 20° and use all four screws are standalone and require no supplemental fixation. Tesera-K SA ALIF assemblies (cage, screws, coverplate) that contain cages with lordotic angles greater than or equal to 20° or if the surgeon chose to use fewer than four screws are considered non standalone and require supplemental fixation cleared by the FDA for use in the lumbosacral spine.
The Kyocera Medical Technologies, Inc. (KMTI) Tesera-K XL System is indicated for intervertebral body fusion procedures in skeletally mature patients with degenerative disc disease (DDD) at one or two contiguous levels from L2 to S1. KMTI Tesera-K XL System implants are to be used with autogenous or allogenic bone graft. Patients should be skeletally mature and have at least six weeks of non-operative treatment prior to implantation. The KMTI Tesera-K XL System is a non-standalone system and is required to be used with additional supplemental fixation that have been cleared by the FDA for use in the lumbar spine.

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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K261353 510(K) SUMMARY

Submitter's Name:	Kyocera Medical Technologies, Inc.
Submitter's Address:	1289 Bryn Mawr Ave., Ste. A Redlands, CA 92374
Submitter's Telephone:	909-557-2360
Contact Person:	Hannah Taggart, MS, RAC ATS Colorado Springs 719- 457-1152 htaggart@atslab.com
Date Summary was Prepared:	July 10, 2026
Trade or Proprietary Name:	Tesera-K Anterior Lumbar Interbody Fusion (ALIF) System Tesera-K XL System Lumbar Anchor System
Device Classification Name:	Intervertebral Fusion Device With Integrated Fixation, Lumbar
Classification & Regulation #:	Class II per 21 CFR §888.3080
Product Code:	OVD, MAX
Classification Panel:	Orthopedic

DESCRIPTION OF THE DEVICE SUBJECT TO PREMARKET NOTIFICATION:

The Kyocera Medical Technologies, Inc. (KMTI) Lumbar Anchor System consists of implants designed to integrate with the KMTI Tesera-K SA Anterior Lumbar Interbody Fusion (ALIF) System and the Tesera-K XL System to support foraminal height and decompression between lumbar or lumbosacral vertebral bodies during spinal correction and fusion as well as reusable instruments to assist in anchor implantation.

The Lumbar Anchor implants are offered in both traditionally machined Ti-6Al-4V per ASTM F136 and additively manufactured from Ti-6Al-4V per ASTM F3001. The Lumbar Anchor implants are non-sterile packaged and intended to be steam sterilized by the end user. The Lumbar Anchors implants are offered in three sizes to meet patient anatomical needs.

INDICATIONS FOR USE

The Kyocera Medical Technologies, Inc. (KMTI) Lumbar Anchor System is indicated for use with the KMTI Tesera-K Anterior Lumbar Interbody Fusion (ALIF) System and Tesera-K XL System.

The KMTI Tesera-K ALIF System is indicated for interbody fusion procedures in skeletally mature patients with degenerative disc disease (DDD) in the lumbar spine at one or two contiguous levels from L2 to S1. DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. These DDD patients may have up to Grade 1 spondylolisthesis or retrolisthesis at the involved level(s). KMTI Tesera-K ALIF System implants are to be used with autogenous bone graft. Patients should be skeletally mature and have at least six months of non-operative treatment.

Tesera-K SA ALIF cages are intended to be implanted from a direct anterior surgical approach only. Tesera-K SA ALIF cages are intended to be used with the coverplate and screws provided or with the KMTI Lumbar Anchor System. Tesera-K SA ALIF assemblies (cage, lumbar anchors, screws and coverplate) featuring one or more lumbar anchors are considered non-standalone and require supplemental fixation cleared by the FDA for use in the lumbosacral spine. The coverplate assembly is required to be used if any anchors are implanted.

Tesera-K SA ALIF cages are intended to be implanted from a direct anterior surgical approach only. Tesera-K SA ALIF cages are intended to be used with the coverplate and screws provided. Tesera-K SA ALIF assemblies (cage, screws, coverplate) that contain cages with lordotic angles less than 20° and use all four screws are standalone and require no supplemental fixation. Tesera-K SA ALIF assemblies (cage, screws, coverplate) that contain cages with lordotic angles greater than or equal to 20° or if the surgeon chose to use fewer than four screws are considered non standalone and require supplemental fixation cleared by the FDA for use in the lumbosacral spine.

The Kyocera Medical Technologies, Inc. (KMTI) Tesera-K XL System is indicated for intervertebral body fusion procedures in skeletally mature patients with degenerative disc disease (DDD) at one or two contiguous levels from L2 to S1. KMTI Tesera-K XL System implants are to be used with autogenous or allogenic bone graft. Patients should be skeletally mature and have at least six weeks of non-operative treatment prior to implantation. The KMTI Tesera-K XL System is a non-standalone system and is required to be used with additional supplemental fixation that have been cleared by the FDA for use in the lumbar spine.

TECHNOLOGICAL CHARACTERISTICS

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 the same between the subject and predicates:

- Indications for Use
- Structure and Function
- Materials of manufacture
- Sterility
- Sizes
- Manufacturing and Biocompatibility

Predicate Devices

510k Number	Trade or Proprietary or Model Name	Manufacturer	Product Code	Predicate Type
K212980	Tesera-k ALIF System	KMTI	OVD, MAX	Primary
K222554	EL Captain ALIF	Astura Medical	OVD	Additional
K242771	Tesera-k XL System	KMTI	MAX, OVD	Additional

The subject device is different from the predicate devices in the following ways:

- There subject anchors are provided in traditionally manufactured and additively manufactured options. The predicate system does not offer an additively manufactured anchor. This difference was addressed through dynamic cantilever bend testing side-by-side with a cleared predicate anchor to show substantial equivalence.

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 Tesera-K SA ALIF System with Lumbar Anchor System has been tested in the following test modes:

- Dynamic Cantilever Bending per ASTM F2193
- Dynamic Axial Compression per ASTM F2077
- Dynamic Compression Shear per ASTM F2077

The results of this non-clinical testing show that the strength of the Tesera-K SA ALIF System with Lumbar Anchor 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 Tesera-K SA ALIF System and Tesera-K XL System with Lumbar Anchor System is substantially equivalent to the predicate device.