March 20, 2025

Kyocera Medical Technologies, Inc.
℅ Nathan Wright
Engineer & Regulatory Specialist
Empirical Technologies
4628 Northpark Drive
Colorado Springs, Colorado 80918

Re: K242771
Trade/Device Name: Tesera-k PL System and Tesera-k XL System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: MAX, OVD
Dated: February 21, 2025
Received: February 21, 2025

Dear Mr. Nathan Wright:

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 System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 systems (QS) regulation (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,

Katherine D. Kavlock -S

for

Brent L. 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.

Submission Number *(if known)*

K242771

Device Name

Tesera-k PL System and Tesera-k XL System

Indications for Use *(Describe)*

Tesera-k Lumbar System:
The Kyocera Medical Technologies, Inc. (KMTI) Tesera-k PL 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 Teresa-K PL System implants are to be used with autogenous or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft. Patients should be skeletally mature and have at least six months of non-operative treatment prior to implantation. The KMTI Tesera-k PL 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.

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 arare to be used with autogenous or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft. Patients should be skeletally mature and have at least six months 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.

K242771 510(K) SUMMARY

Submitter's Name:	Kyocera Medical Technologies, Inc. (KMTI)
Submitter's Address:	1200 California Street, Suite 210 Redlands, California 92374
Submitter's Telephone:	909-557-2360
Contact Person:	Nathan Wright, MS, RAC Empirical Technologies 1-719-351-0248 nwright@empiricaltech.com
Date Summary was Prepared:	December 18, 2024
Trade or Proprietary Name:	Tesera-k PL System and Tesera-k XL System
Device Classification Name:	Intervertebral Fusion Device with Integrated Fixation, Lumbar
Classification & Regulation #:	Class II per 21 CFR §888.3080
Product Code:	MAX, OVD
Classification Panel:	Orthopedic – Spinal (DHT6B)

DESCRIPTION OF THE DEVICE SUBJECT TO PREMARKET NOTIFICATION:

The Tesera-k Lumbar System (Tesera-k PL (Tk-PL) System and Tesera-k XL System (Tk-XL) System) consist of interbody fusion implants intended to provide stability and facilitate fusion in the lumbar spine.

The Tesera-k PL System implants are offered with straight or curved profiles to accommodate posterior or transforaminal surgical approaches. The Tesera-k PL implants are additively manufactured then machined from Titanium alloy (Ti-6Al-4V ELI) per ASTM F3001.

The Tesera-k XL System implants are offered in a straight profile for the direct lateral surgical approach. The Tesera-k XL cages are additively manufactured then machined from Titanium alloy (Ti-6Al-4V ELI) per ASTM F3001. The Tesera-k XL Bone Screws and Locking Assemblies are machined from Titanium alloy (Ti-6Al-4V ELI) per ASTM F136.

The Tesera-k PL and Tesera-k XL Systems are non-standalone systems and must be used in conjunction with FDA-cleared lumbosacral supplemental fixation.

INDICATIONS FOR USE

The Kyocera Medical Technologies, Inc. (KMTI) Tesera-k PL 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 Teresa-K PL System implants are to be used with autogenous or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft. Patients should be skeletally mature and have at least six months of non-operative treatment prior to implantation. The KMTI Tesera-k PL 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.

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 comprised of cancellous and/or corticocancellous bone graft. Patients should be skeletally mature and have at least six months 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 predicates included in this submission were selected based on the best practices described in the FDA Draft Guidance document *Best Practices for Selecting a Predicate Device to Support a Premarket Notification [510(k)] Submission*. 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

Predicate Devices

510k Number	Trade or Proprietary or Model Name	Manufacturer	Product Code	Predicate Type
K172816	TiGer Shark System	Choice Spine, LP	MAX	Primary
K133614	Aleutian IBF System	K2M, Inc.	MAX, MQP, ODP	Additional
K172341	NuVasive Modulus TLIF Interbody System	NuVasive, Inc.	MAX, PHM	Additional
K181655	Renovis S180 Lateral Lumbar Interbody System	Renovis Surgical Technologies	MAX	Additional
K212980	Tesera-k ALIF System	Kyocera Medical Technologies, Inc.	MAX, OVD	Additional

PERFORMANCE DATA

The subject device has been tested in the following test modes:

- ASTM F2077 Static Axial Compression
- ASTM F2077 Dynamic Axial Compression
- ASTM F2077 Static Compression Shear
- ASTM F2077 Dynamic Compression Shear
- ASTM F2267 Subsidence
- Expulsion
- ASTM F1147 Tensile Strength
- ASTM F1160 Shear Fatigue
- ASTM F1978 Abrasion

The results of this non-clinical testing show that the strength of the Tesera-k PL and Tesera-k XL Systems are sufficient for their intended use and are substantially equivalent to legally marketed predicate devices.

CONCLUSION

The overall technology characteristics and mechanical performance data lead to the conclusion that the Tesera-k PL and Tesera-k XL Systems are substantially equivalent to the predicate devices.