January 7, 2022

Kyocera Medical Technologies, Inc.
% Nathan Wright, MS
Engineer and Regulatory Specialist
Empirical Testing Corp.
4628 Northpark Drive
Colorado Springs, Colorado 80918

Re: K212980
Trade/Device Name: Tesera-k ALIF System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: OVD, MAX
Dated: December 16, 2021
Received: December 20, 2021

Dear Mr. 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 (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,

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K212980

Device Name
Tesera-k ALIF System

Indications for Use *(Describe)*
The Kyocera Medical Technologies, Inc. (KMTI) Tesera-k Anterior Lumbar Interbody Fusion (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 nonoperative treatment. The Tesera-k ALIF System implants are available in standalone (Tesera-k SA) and non-standalone (Tesera-k A) configurations.

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.

Tesera-k A ALIF cages are monolithic and do not interface or mate with any additional implants. Tesera-k A ALIF cages may be implanted from direct anterior or oblique insertion angle. Tesera-k A ALIF cages are non-standalone and require supplemental fixation cleared by the FDA for use in the lumbosacral 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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K212980 510(K) SUMMARY

Submitter's Name:	Kyocera Medical Technologies, Inc.
Submitter's Address:	1200 California Street, Ste. 210 Redlands, CA 92374
Submitter's Telephone:	(909) 557-2360
Contact Person:	Nathan Wright MS Empirical Testing Corp. 719-351-0248 nwright@empiricaltech.com
Date Summary was Prepared:	September 16, 2021
Trade or Proprietary Name:	Tesera-k ALIF System
Common or Usual Name:	Intervertebral body fusion device
Classification:	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) Tesera-k Anterior Lumbar Interbody Fusion (ALIF) System implants support foraminal height and decompression between lumbar or lumbosacral vertebral bodies during spinal correction and fusion as well as reusable instruments to assist in endplate preparation and implantation. The Tesera-k ALIF System implants are available as a monolith without integrated fixation (Tesera-k A) or as a standalone with integrated fixation (Tesera-k SA) and are additively manufactured from Ti-6Al-4Vper ASTM F2924. The Tesera-k SA constructs includes screws and a coverplate manufactured from Ti-6Al-4V per ASTM F136 from the Tesera SA ALIF System (K193320, K131122, K140106, and K180502). The Tesera-k ALIF implants are sterile packaged and inserted via a direct anterior or oblique anterior surgical approach. The Tesera-k ALIF implants are offered in a variety of sizes and lordosis options to meet patient anatomical needs.

INDICATIONS FOR USE

The Kyocera Medical Technologies, Inc. (KMTI) Tesera-k Anterior Lumbar Interbody Fusion (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. The Tesera-k ALIF System implants are available in standalone (Tesera-k SA) and non-standalone (Tesera-k A) configurations.

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.

Tesera-k A ALIF cages are monolithic and do not interface or mate with any additional implants. Tesera-k A ALIF cages may be implanted from direct anterior or oblique insertion angle. Tesera-k A ALIF cages are non-standalone and require supplemental fixation cleared by the FDA for use in the lumbosacral 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 identical between the subject and predicates:

- Indications for Use
- Technological characteristics
- Materials of manufacture

Table 5-1 Predicate Devices

510k Number	**Trade or Proprietary Name**	**Manufacturer**	**Predicate Type**
K193320	KMTI Tesera SA Anterior Lumbar Interbody Fusion System	Kyocera Medical Technologies, Inc.	Primary
K200879	SeaSpine Meridian System	SeaSpine Orthopedics Corporation	Additional
K190483	SPIRA Open Matrix ALIF	Camber Spine Technologies	Additional
K131612	AnyPlus ALIF PEEK Lumbar Fusion Cage	GS Medical	Additional
K092193	Spinal USA Intervertebral Body Fusion Device ALIF	Spinal USA	Additional
K183705	IdentiTi Porous Ti Interbody System ALIF	Alphatec Spine, Inc.	Additional

PERFORMANCE DATA

The Tesera-k ALIF System has been tested in the following test modes:

- Static and dynamic axial compression per ASTM F2077
- Static and dynamic compression shear per ASTM F2077
- Subsidence per ASTM F2267

The results of this non-clinical testing show that the strength of the Tesera-k ALIF 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 ALIF System is substantially equivalent to the predicate device.