December 22, 2022

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

Re: K223105
Trade/Device Name: Tesera-K SC System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: OVE, ODP
Dated: September 30, 2022
Received: September 30, 2022

Dear 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 (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,

Katherine D. Kavlock -S

for
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K223105

Device Name
Tesera-K SC System

Indications for Use *(Describe)*
The KMTI Tesera-K SC System is indicated for intervertebral body fusion procedures in skeletally mature patients with cervical degenerative disc disease at one or two levels from C2-T1. KMTI Tesera-K SC System implants are to be used with autogenous bone graft. Patients should be skeletally mature and have at least six weeks of non-operative treatment prior to implantation.

The KMTI Tesera-K SC System is a stand-alone system when used with the locking bolt and bone screws provided and requires no additional supplemental fixation. When used as a stand-alone system, the cages require the use of two (2) bone screws and the locking bolt.

When used without the locking bolt and two screws, the KMTI Tesera-K SC System is a non-standalone system and requires additional supplemental fixation cleared by the FDA for use in the cervical spine to augment stability and may only be used at one level.

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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K223105 - 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 Empirical Technologies 1-719-351-0248 nwright@empiricaltech.com
Date Summary was Prepared:	September 29, 2022
Trade or Proprietary Name:	Tesera-K SC System
Classification Name:	Intervertebral Body Fusion Device
Classification:	Class II per 21 CFR §888.3080
Product Code:	OVE, ODP
Classification Panel:	Orthopedic – Spinal (DHT6B)

DESCRIPTION OF THE DEVICE SUBJECT TO PREMARKET NOTIFICATION:

The Tesera-K SC System (Tesera-K SC) is a spinal fusion system consisting of additively manufactured interbody devices and machined titanium bone screws and locking bolts. It is designed to provide mechanical support to the cervical spine while arthrodesis occurs. The Tesera-K SC implants are available in a variety of lordosis and footprint options with a superior and inferior porous face and internal lattice structure to offer increased capacity for bone growth.

The Tesera-K SC cages are additively manufactured then machined from Titanium alloy (Ti-6Al-4V) per ASTM F2924, and the bone screws and locking bolts are machined from Titanium alloy (Ti-6Al-4V) per ASTM F136.

The Tesera-K SC System may be implanted as a standalone with two internal fixation screws and the locking bolt and without supplemental fixation or may be implanted as a non-standalone system without the internal fixation screws and locking bolt but with FDA-cleared supplemental fixation.

INDICATIONS FOR USE

The KMTI Tesera-K SC System is indicated for intervertebral body fusion procedures in skeletally mature patients with cervical degenerative disc disease at one or two levels from C2-T1. KMTI Tesera-K SC System implants are to be used with autogenous bone graft. Patients should be skeletally mature and have at least six weeks of non-operative treatment prior to implantation.

The KMTI Tesera-K SC System is a stand-alone system when used with the locking bolt and bone screws provided and requires no additional supplemental fixation. When used as a stand-alone system, the cages require the use of two (2) bone screws and the locking bolt.

When used without the locking bolt and two screws, the KMTI Tesera-K SC System is a non-standalone system and requires additional supplemental fixation cleared by the FDA for use in the cervical spine to augment stability and may only be used at one level.

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
- Principle of operation
- Structural support mechanism
- Materials of manufacture
- Mechanical strength
- Cage Sizes
- Screw Sizes
- Manufacturing and Biocompatibility

Predicate Devices

510k Number	Trade or Proprietary or Model Name	Manufacturer	Product Code	Predicate Type
K212853	Cervical Stand-Alone System	Eminent Spine, LLC	OVE	Primary
K211111	SureMAX-SA Cervical Standalone System	Additive Implants, Inc.	OVE	Additional
K173077	Cavetto®-SA Cervical Cage System	Neurostructures, Inc	OVE	Additional
K153250	Tesera SC Stand-Alone Cervical Fusion (ACF)	Renovis Surgical Technologies, Inc.	OVE, ODP	Additional
K212980	Tesera-k ALIF System	Kyocera Medical Technologies, Inc.	OVD, MAX	Reference

PERFORMANCE DATA

The Tesera-K SC 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
- Static and dynamic torsion per ASTM F2077
- Subsidence per ASTM F2267

The results of this non-clinical testing show that the strength of the Tesera-K SC 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 SC System is substantially equivalent to the predicate devices.