February 4, 2020

Kyocera Medical Technologies, Inc.
℅ Sharyn Orton
Senior Consultant
MEDIcept, Inc.
200 Homer Ave
Ashland, Massachusetts 01721

Re: K193320
Trade/Device Name: KMTI Tesera SA Anterior Lumbar Interbody Fusion (ALIF) System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: OVD
Dated: December 17, 2019
Received: December 18, 2019

Dear Dr. Orton:

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,

for
Brent L. Showalter, Ph.D.
Assistant Director (Acting)
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K193320

Device Name
KMTI Tesera SA Anterior Lumbar Interbody Fusion (ALIF) System

Indications for Use *(Describe)*
The KMTI Tesera SA Anterior Lumbar Interbody Fusion (ALIF) System is indicated for intervertebral body fusion procedures in skeletally mature patients with degenerative disc disease (DDD) of the lumbar spine at one or two contiguous levels from L2-S1. Degenerative disc disease 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 SA 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 KMTI Tesera SA ALIF System is a standalone device and is intended to be used with the cover plate and screws provided and requires no additional supplementary fixation. The anterior cover plate must be utilized whenever the device is implanted using the bone screws provided. Should the physician choose to use fewer than the four screws provided, additional supplemental fixation cleared by the FDA for use in the lumbar spine must be used. Supplemental fixation, cleared by the FDA for use in the lumbosacral spine, must be used with implants ≥20°.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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Traditional 510(k) Premarket Notification Summary
as required by 21 CFR 807.92(a) K193320

A) Submitted by: Kyocera Medical Technologies, Inc.
1200 California St. Suite 210
Redlands, CA 92374
Phone: 909-557-2360
Fax: 909-839-6269

Official Contact: Anthony DeBenedictis
Divisional Vice President of Quality Assurance

Consultant: Sharyn Orton, Ph.D.
MEDIcept, Inc.
200 Homer Ave
Ashland, MA 01721

B) Classification Name: Intervertebral Fusion Device With Bone Graft, Lumbar

Common Name:	Intervertebral body fusion device
Proprietary Name:	KMTI Tesera SA Anterior Lumbar Interbody Fusion System
Device Class:	Class II
Regulations and Product Code:	21 CFR 888.3080 OVD
Classification panel:	Orthopedic

C) Predicates: Primary: K131122 Renovis S128 Anterior Lumbar Interbody Fusion (ALIF) System
Secondary: K140106 Renovis S128 Anterior Lumbar Interbody Fusion (ALIF) System
Secondary: K180502 Renovis S128 Anterior Lumbar Interbody Fusion (ALIF) System

D) Date Prepared: January 31, 2020

E) Device Description:

The Kyocera Medical Technologies, Inc. Tesera SA Anterior Lumbar Interbody Fusion (ALIF) System is a change to the FDA cleared Kyocera S128 Anterior Lumbar Interbody Fusion (ALIF) System (Ti6Al4V and PEEK cages, Cover Plate, screws and instruments; K131122, K140106, and K180502). Only the Ti6Al4V cages are relevant to this application which describes a change in manufacturing and material standard. There are no other changes in cage dimensions (L, W, H and lordosis), sterilization, packaging or shelf-life. The new system will be marketed as the Tesera SA Anterior Lumbar Interbody Fusion (ALIF) System ("Tesera SA ALIF System") and will include Ti6Al4V cages only.

The Tesera SA ALIF System includes cages of a variety of lengths, widths, heights, and lordosis to suit the individual pathology and anatomical conditions of the patient. The different shape of the footprint allows for different surgical approaches for insertion. Tesera SA ALIF System cages are standalone when implanted with the Cover Plate and screws with the exception of implants $\geq 20^0$ which require supplemental fixation.

- The Ti6Al4V is compliant with ASTM F2924 Standard Specification for Additive Manufacturing Titanium-6 Aluminum-4 Vanadium with Powder Bed Fusion

The Tesera SA ALIF System cages that are the subject of this application are gamma sterilized.

The system also includes the previously FDA cleared Cover Plate and screws; previously FDA cleared and new instruments to allow for implant determination, trialing and disc preparation. New instruments are manufactured from stainless steels compliant with ASTM A564 Standard Specification for Hot-Rolled and Cold-Finished Age-Hardening Stainless Steel Bars and Shapes.

F) Intended Use/Indications For Use:

The KMTI Tesera SA Anterior Lumbar Interbody Fusion (ALIF) System is indicated for intervertebral body fusion procedures in skeletally mature patients with degenerative disc disease (DDD) of the lumbar spine at one or two contiguous levels from L2-S1. Degenerative disc disease 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 SA 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 KMTI Tesera SA ALIF System is a stand-alone device and is intended to be used with the cover plate and screws provided and requires no additional supplementary fixation. The anterior cover plate must be utilized

whenever the device is implanted using the bone screws provided. Should the physician choose to use fewer than the four screws provided, additional supplemental fixation cleared by the FDA for use in the lumbar spine must be used. Supplemental fixation, cleared by the FDA for use in the lumbosacral spine, must be used with implants ≥20°.

G) Substantial Equivalence Comparison and Discussion

The Tesera SA ALIF System has the same Indications for Use as the predicate devices. The cages are additively manufactured; have the same dimensions and sizes, are packaged and gamma sterilized the same as the predicate cages. The new cages are manufactured to ASTM F2924, which is appropriate for additive manufacturing. The Tesera SA ALIF System cages are additively manufactured using the same technology and material standard as the FDA cleared K181655 Kyocera S180 Lateral Lumbar Interbody Fusion (LLIF) System cages (reference device). The manufacturing change has been validated.

H) Performance – Bench

The new changes were assessed for risk and successful dynamic shear compression testing conducted.

I) Compliance with Standards or FDA Guidance

The Tesera SA ALIF System complies with the following:

- ASTM F2077-18 Test Methods For Intervertebral Body Fusion Devices
- ASTM E8/E8M-16 Standard Test Methods for Tension Testing of Metallic Materials
- Guidance for Industry and FDA Staff - Class II Special Controls Guidance Document: Intervertebral Body Fusion Device, June 2007

Conclusion

The change in manufacturing and material standard do not result in new or different issues of safety or effectiveness associated with the new cages.

The Tesera SA ALIF System is substantially equivalent to the predicate devices.