August 30, 2021

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

Re: K212070
Trade/Device Name: KMTI S141 Lumbar Interbody Fusion System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: MAX
Dated: August 20, 2021
Received: August 23, 2021

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,

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

4. INDICATIONS FOR USE STATEMENT

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020

Indications for Use

510(k) Number *(if known)*

K212070

Device Name

Kyocera Medical Technologies, Inc. (KMTI) S141 Lumbar Interbody Fusion System

Indications for Use *(Describe)*

The KMTI S141 Lumbar Interbody Fusion 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 S141 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 S141 System must be used with supplemental fixation cleared by 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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510(K) SUMMARY

Submitter's Name:	Kyocera Medical Technologies, Inc.
Submitter's Address:	1200 California St, Suite 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:	July 1, 2021
Trade or Proprietary Name:	KMTI S141 Lumbar Interbody Fusion System
Common or Usual Name:	Intervertebral body fusion device
Classification:	Class II per 21 CFR §888.3080
Product Code:	MAX
Classification Panel:	Orthopedic Devices

DESCRIPTION OF THE DEVICE SUBJECT TO PREMARKET NOTIFICATION:

The Kyocera Medical Technologies, Inc. (KMTI) KMTI S141 Lumbar Interbody Fusion System (also called S141 LIF System) consists of cages which can be inserted between two lumbar or lumbosacral vertebral bodies to give support and correction during lumbar interbody fusion. The S141 LIF System includes the Tesera-P, Tesera-T, Tesera-ST, PEEK Straight TLIF, and PEEK TLIF families. The implants are offered in additively manufactured Titanium Alloy (Titanium-6Aluminum-4Vanadium) per ASTM F2924 and PEEK (Polyetheretherketone) per ASTM F2026.This submission updates the subject titanium alloy material specifications and standards, modifies the additive printing process, and expands the product line for the previously cleared S141 Lumbar Interbody Fusion System.

The KMTI S141 Lumbar Interbody Fusion System is comprised of a variety of implant sizes to accommodate various patient anatomy and pathology, and associated instrumentation. The implants may be inserted via an open or minimally invasive approach. The Tesera P and PEEK PLIF use a posterior approach. The PEEK Straight TLIF, PEEK TLIF, Tesera ST, and Tesera T use an oblique approach. The hollow geometry of the implants allows them to be packed with autogenous bone graft. The superior and inferior surfaces of the Titanium Alloy implant consist of Tesera porous titanium structure to facilitate osseous integration. The superior and inferior surfaces of the S141 PEEK devices have "teeth" to help prevent the device from migration after surgically positioned. Additionally, the S141 PEEK devices contain tantalum markers (per ASTM F560) to assist the surgeon with proper placement of the device. The implants are provided terminally sterilized via gamma irradiation prior to end-user receipt.

INDICATIONS FOR USE

The KMTI S141 Lumbar Interbody Fusion 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 S141 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 S141 System must be used with supplemental fixation cleared by FDA for use in the lumbar spine.

The indications for use for the KMTI LIF System are identical to those of the primary predicate.

TECHNICAL CHARACTERISTICS

The purpose of this system is to expand the product line of the KMTI S141 Lumbar Interbody Fusion System with additional sizes offered and to modify the material and manufacturing method for the KMTI S141 devices which were previously cleared. The KMTI S141 Lumbar Interbody Fusion System is made from Ti-6Al-4V ELI per ASTM F136 or Ti-6Al-4V per F2924 or from PEEK per ASTM F2026 with tantalum per ASTM F560. 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
- Structural support mechanism
- Sizes

Table 5-1 Predicate Devices

510k Number	**Trade or Proprietary or Model Name**	**Manufacturer**	**Predicate Type**
K170888, K143126	Renovis S141 Lumbar Interbody Fusion System	Renovis Surgical Technologies	Primary
K181655	Renovis S180 Lateral Lumbar Interbody Fusion System	Renovis Surgical Technologies	Additional
K171657	ShurFit 2C Lumbar Interbody Fusion System	Precision Spine, Inc.	Additional
K113561	TM Ardis® Interbody System	Zimmer Trabecular Metal Technology, Inc.	Additional
K201605	EIT Cellular Titanium® TLIF Cage	EIT Emerging Implant Technologies GmbH	Additional

PERFORMANCE TESTING SUMMARY

In support of this Special 510(k) Device Modification Premarket Notification, Kyocera Medical Technologies, Inc. has conducted mechanical testing to demonstrate that the modifications to the

S141 Lumbar Interbody Fusion System provide adequate and substantially equivalent mechanical strength for their intended use.

CONCLUSION

The subject modified KMTI S141 Lumbar Interbody Fusion System is very similar to previously cleared Renovis S141 Lumbar Interbody Fusion System. The subject KMTI S141 Lumbar Interbody Fusion System has similar intended uses, indications, technological characteristics, and principles of operation as the predicate devices. The modifications raise no new types of safety or effectiveness questions. The overall technology characteristics and mechanical performance data lead to the conclusion that the KMTI S141 Lumbar Fusion System is substantially equivalent to the predicate devices.