April 21, 2023

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

Re: K230808
Trade/Device Name: PEEK 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: March 23, 2023
Received: March 23, 2023

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 Showalter -S

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: 0MB No. 0910-0120
Expiration Date: 06/30/2023
See *PRA Statement below.*

Submission Number *(if known)*

K230808

Device Name

PEEK SA Anterior Lumbar Interbody Fusion (ALIF) System

Indications for Use *(Describe)*

The KMTI PEEK 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-S 1. Degenerative disc disease is defined as discogenic back pain with degeneration of the disc confirmed by history and radio graphic studies. These DDD patients may have up to Grade 1 spondylolisthesis or retrolisthesis at the involved level(s). KMTI PEEK 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 PEEK SA ALI F 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 surgeon choose to use fewer than the four screws provided, additional supplemental fixation cleared by the FDA for use inthe lumbar spine must be used. Supplemental fixation, cleared by the FDA for use inthe lumbosacral spine, must be used with implants ≥ 20°.

Type of Use *(Select one* or *both,* as *applicable)*

[X] Prescription Use (Part 21 CFR 801 Subpart D} [ ] Over-The-Counter Use (21 CFR 801 Subpart C}

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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10. 510(K) SUMMARY

Submitter's Name:	Kyocera Medical Technologies, Inc.
Submitter's Address:	1200 California Street Suite 210 Redlands, CA 92374
Submitter's Telephone:	909-557-2360
Contact Person:	Nathan Wright MS Empirical Technologies 719-351-0248 nwright@empiricaltech.com
Date Summary was Prepared:	March 23 2023
Trade or Proprietary Name:	PEEK SA Anterior Lumbar Interbody Fusion (ALIF) System
Device Classification Name:	Intervertebral Fusion Device with Integrated Fixation, Lumbar
Classification & Regulation #:	Class II per 21 CFR §888.3080
Product Code:	OVD
Classification Panel:	Orthopedic Devices – Spinal Devices (DHT6B)

DESCRIPTION OF THE DEVICE SUBJECT TO PREMARKET NOTIFICATION:

The KMTI PEEK SA Anterior Lumbar Interbody Fusion (ALIF) System consists of PEEK cages, titanium screws, and a titanium cover plate. The KMTI PEEK SA ALIF System cages are intended to be used with the bone screws, the anterior cover plate assembly (cover plate), and do not require supplementary fixation systems unless less than four bone screws are utilized or cage lordosis is ≥20°. The screws protrude through the interbody portion of the cage implant and stabilize the vertebral body while preventing expulsion of the cage implant. The KMTI PEEK SA ALIF System offers hexalobe drive with both fixed and variable angle screw options. The fixed angle screw option provides a tighter fit with the cage than the variable angle screws while the variable angle screw option provides more clearance between the cage and the screw than the fixed screw, which allows for a small amount of screw angulation. The accompanying cover plate is designed to resist screw back-out and must be used when the screws are implanted. The cover plate assembly and screw are part of the implant construct.

The KMTI PEEK SA ALIF System cages are available in a variety of sizes to suit the individual patient anatomical needs.

The purpose is to offer non-sterile packaging for cage sizes in the PEEK SA ALIF System (formerly S128 ALIF System) previously cleared for sterile packaging only.

INDICATIONS FOR USE

The KMTI PEEK 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 radio graphic studies. These DDD patients may have up to Grade 1 spondylolisthesis or retrolisthesis at the involved level(s). KMTI PEEK 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 PEEK 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°.

TECHNOLOGICAL CHARACTERISTICS

The subject and predicate have identical technological characteristics. There are no differences between the subject and predicate devices that raise questions regarding the safety and effectiveness of the subject device. Specifically, the following characteristics are identical between the subject and predicates.

- Indications for Use
- Principle of Operation
- Structural Support Mechanism
- Materials of Manufacture
- Sterilization
- Sizes

Predicate Devices

510k Number	Trade or Proprietary or Model Name	Manufacturer	Predicate Type
K180502	S128 Anterior Lumbar Interbody Fusion (ALIF) System	Renovis Surgical Technologies Inc	Primary
K131122	S128 Anterior Lumbar Interbody Fusion (ALIF) System	Renovis Surgical Technologies Inc	Additional

PERFORMANCE DATA

Performance testing was not required in this submission for the modifications proposed. Changes in sterilization were validated according to ISO 17665-1.

CONCLUSION

The overall technology characteristics are identical between the subject and predicates which leads to the conclusion that the PEEK SA ALIF System is substantially equivalent to the predicate device.