August 17, 2022

TDM Co. Ltd.
% Jeena Mathai
President
Eerkie Corporation
4027 Runnymeade Dr
Collegeville, Pennsylvania 19426

Re: K221844
Trade/Device Name: TDM Lumbar Interbody Fusion Cage System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: MAX
Dated: June 15, 2022
Received: June 24, 2022

Dear Jeena Mathai:

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

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)*
K221844

Device Name
TDM Lumbar Interbody Fusion Cage System

Indications for Use *(Describe)*
TDM Lumbar Interbody Fusion Cage System is indicated for intervertebral body fusion procedures in skeletally mature patients with degenerative disc disease (DDD) at one or two contiguous levels from L2-S1, who have had six months of non-operative treatment. DDD is defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies. These DDD patients may also have up to Grade 1 spondylolisthesis or retrolisthesis at the involved level(s). This device is to be used with autogenous bone graft. TDM Lumbar Interbody Fusion Cage System is to be used with supplemental fixation.

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.

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510(k) SUMMARY

TDM's
TDM Lumbar Interbody Fusion Cage System

Sponsor:	Manufacturer	TDM Co. Ltd. 69, Cheomdan Venture So-ro, 37 beon-gil, Buk-gu, Gwangju, Korea 61003
	Official Contact	Jung Wook, Choi
	Phone:	+82-62-971-7460
	Fax:	+82-62-971-7461
	Contact Person	Jeena Mathai mgsharemg@gmail.com
	Date:	August 12, 2022
Device Name:	TDM Lumbar Interbody Fusion Cage System	
Common Name:	Intervertebral Body Fusion Device	
Classification Name:	Intervertebral Body Fusion Device, Lumbar	
Classification Number:	21 CFR 888.3080	
Product Code/Classification:	MAX, class II	
Description:	The TDM Lumbar Interbody Fusion Cage System (EVERGREEN PEEK PLIF Cage, LIME PEEK TLIF Cage, and PORTIA HYBRID TLIF cage) consists of intervertebral body fixation devices intended for use as an aid in spinal fixation. This system is fabricated and manufactured from PEEK as described by ASTM F2026. The Tantalum and Titanium marker used for this product is made to the voluntary standard of ASTM F560 and ASTM F136. The devices are available in a variety of different sizes and heights to match more closely the patient's anatomy. The ends of the implants have machined teeth which are designed to engage with the vertebral body end plates. The EVERGREEN PEEK PLIF Cages are to be implanted via posterior approach. Two PLIF PEEK cages are placed on each side of the interbody space (right and left). The LIME PEEK TLIF Cages and PORTIA HYBRID TLIF cages are dedicated to transforaminal approach. TLIF technique involves placing only one bone graft spacer in the middle of the interbody space, without retraction of the spinal nerves.	
Intended Use:	TDM Lumbar Interbody Fusion Cage System is indicated for intervertebral body fusion procedures in skeletally mature patients with degenerative disc disease (DDD) at one or two contiguous levels from L2-S1, who have had six	

	months of non-operative treatment. DDD is defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies. These DDD patients may also have up to Grade 1 spondylolisthesis or retrolisthesis at the involved level(s). This device is to be used with autogenous bone graft. TDM Lumbar Interbody Fusion Cage System is to be used with supplemental fixation.
Performance Data:	Non-clinical testing was performed to demonstrate that the subject TDM Lumbar Interbody Fusion Cage System is substantially equivalent to the predicate device. The following testing was performed in accordance with the ASTM F2077, and ASTM F2267: - Static Axial Compression - Dynamic Axial Compression - Static Torsion - Static Shear - Dynamic Shear - Subsidence The nonclinical tests demonstrate that the TDM Lumbar Interbody Fusion Cage System is as safe, as effective, and performs as well as or better than the legally marketed predicate devices.
Predicate Device:	Primary predicate: GS Medical Co. – AnyPlus PEEK Cage (K100516) Additional predicate: Huvexel Co. Ltd. – Galaxy PEEK Cage (K122872)
Reference Devices:	K171808 - TDM Small Locking Plate and Screw System K190830 - TDM Screw System
Technological Characteristics	The TDM Lumbar Interbody Fusion Cage System was shown to be substantially equivalent and has equivalent technological characteristics to its predicate and reference devices through comparison in areas including design, labeling/intended use, material composition, function, range of sizes, and packaging.
Performance and SE Determination:	The TDM Lumbar Interbody Fusion Cage System has been demonstrated to be substantially equivalent to the predicate system(s) with respect to technical characteristics, performance, and intended use. The information provided within this premarket notification supports substantial equivalence of the subject device to the predicate device(s).