January 18, 2024

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

Re: K231860
Trade/Device Name: TDM Screw System
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth Or Threaded Metallic Bone Fixation Fastener
Regulatory Class: Class II
Product Code: HWC
Dated: December 19, 2023
Received: December 19, 2023

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 (the 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 available 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.
Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Shumaya Ali -S

Shumaya Ali, M.P.H.
Assistant Director
DHT6C: Division of Restorative, Repair
and Trauma 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)*
K231860

Device Name
TDM Screw System

Indications for Use *(Describe)*
The TDM Screw Systems are indicated for fixation of fractures, fusions, osteotomies, non-unions, and malunions of bones appropriate for the size of the device.

Cannulated Screw System:
The Cannulated Screw System is intended to be used for fracture of small bones of the hand or foot or small and large bones.

Headless Compression Cannulated Screw System:
The Headless Compression Cannulated Screw System is intended to be used for a wide range of different indications in the hand, wrist and joint fusion (arthrodeses) in the foot and fixation of intra-articular fractures of the humerus, femur and tibia.

Limited Sliding Screw System:
The Limited Sliding Screw System is intended to be used for fracture fixation of the proximal femur.

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.

K231860

510(k) SUMMARY

TDM Screw System

Sponsor:	Manufacturer	TDM Co. Ltd. 69, Cheomdan Venture So-ro, 37 beon-gil, Buk-gu Gwangju, 61003, Republic of Korea
	Official Contact Phone: Fax:	Jungwook Choi +82-62-971-7460 +82-62-971-7461
	Contact Person	Jeena Mathai Eerkie Corporation mgsharemg@gmail.com
	Date:	June 21, 2023
Common Name:	Screw, Fixation, Bone Washer, Bolt Nut	
Device Name:	TDM Screw System	
Classification Name:	Smooth or threaded metallic bone fixation fastener (Primary) Single/multiple component metallic bone fixation appliances and accessories	
Classification Number:	21 CFR 888.3040 (Primary) 21 CFR 888.3030	
Product Code/Classification:	HWC (Primary), HTN class II	
Description:	The TDM Screw Systems consist of a family of devices intended for internal bone fixation of fractures, fusions, osteotomies, non unions, and malunions. The subject devices are constructed from Titanium alloy (ASTM F136) and are comprised of cannulated screws, headless compression cannulated screws, limited sliding screws, compression screws, and washers. The subject devices are available in diameters ranging from 2.5mm to 7.5mm and lengths ranging from 10mm to 125mm. The Washer is available in 5.5mm to 13mm. The Screws are intended for standalone use.	

Indications for Use:	The TDM Screw Systems are indicated for fixation of fractures, fusions, osteotomies, non-unions, and malunions of bones appropriate for the size of the device. Cannulated Screw System: The Cannulated Screw System is intended to be used for fracture of small bones of the hand or foot or small and large bones. Headless Compression Cannulated Screw System: The Headless Compression Cannulated Screw System is intended to be used for a wide range of different indications in the hand, wrist and joint fusion (arthrodeses) in the foot and fixation of intra-articular fractures of the humerus, femur and tibia. Limited Sliding Screw System: The Limited Sliding Screw System is intended to be used for fracture fixation of the proximal femur.
Performance Data:	The following testing was performed in accordance with the ASTM F543-17 and ASTM F1264-16: - Torsional - Pullout - 3-Point Bending The nonclinical tests and engineering analysis demonstrate that the TDM Screw System is as safe, as effective, and is substantially equivalent to the legally marketed predicate device.
Predicate Device:	Primary predicate: TDM Co. Ltd. – TDM Screw Systems (K190830).
Technological Characteristics	The TDM Screw System was shown to be substantially equivalent and has equivalent technological characteristics to its predicate device through comparison in areas including design, labeling/intended use, material composition, function, range of sizes, and packaging.
Performance and SE Determination:	The TDM Screw 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).