December 5, 2024

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

Re: K241128
Trade/Device Name: TDM Plate and Screw System
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/Multiple Component Metallic Bone Fixation Appliances And Accessories
Regulatory Class: Class II
Product Code: HRS, HWC
Dated: April 23, 2024
Received: April 24, 2024

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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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,

CHRISTOPHER FERREIRA -S

Christopher Ferreira, M.S.
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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K241128

Device Name

TDM Plate and Screw System

Indications for Use *(Describe)*

The TDM Plate and Screw Systems are indicated for fixation of fractures, fusions, osteotomies, non-unions, and malunions of bones appropriate for the size of the device.

Mini and Mid Locking Plate and Screw System:
The Mini and Mid Locking Plate and Screw System is intended to be used in the hands, wrist, and small bones in the foot.

Small Locking Plate and Screw System:
The Small Locking Plate and Screw System is indicated for the clavicle, scapula, olecranon, humerus, radius, ulna, tibia, and fibula.

The TDM Screws (1.5mm and larger, Solid and Cannulated) are intended to be used with the plate for internal bone fixation for bone fractures, fusions, osteotomies and non-unions in the foot, hand, wrist, clavicle, scapula, olecranon, humerus, radius, ulna, tibia, and fibula.

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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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

K241128
510(k) SUMMARY

TDM Plate and Screw Systems

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:	November 19, 2024
Device Name:	Bone Fixation, Plates and Screws	
Common Name:	Plate, Fixation, Bone and Screw, Fixation, Bone (Primary) TDM Plate and Screw Systems	
Classification Name:	Single/multiple component metallic bone fixation appliances and accessories Smooth or threaded metallic bone fixation fastener	
Classification Number:	21 CFR 888.3030 (Primary): Single/multiple component metallic bone fixation appliances and accessories 21 CFR 888.3040 : Smooth or threaded metallic bone fixation fastener Class II	
Product Code/Classification:	HRS (Primary), HWC class II	
Description:	The TDM Plate and Screw system consists of a family of flat and contoured plates and screws that make up the Mini and Mid Locking Plate and Screw System and the Small Locking Plate and Screw System. The Plates are constructed from Titanium alloy (Ti-6AL-4V) or pure Titanium (Ti) and come in a variety of configurations. The Plates are intended to be used with locking and non-locking screws and non-locking low profile Screws. The Screw are constructed from Titanium alloy (Ti-6AL-4V) and are available as threaded locking screws, cortical or cancellous, cannulated screws from 1.5mm to 4.0 in diameter and range from 6mm to 100 in length.	

Indications For Use:	The TDM Plate and Screw Systems are indicated for fixation of fractures, fusions, osteotomies, non-unions, and malunions of bones appropriate for the size of the device. Mini and Mid Locking Plate and Screw System: The Mini and Mid Locking Plate and Screw System is intended to be used in the hands, wrist, and small bones in the foot. Small Locking Plate and Screw System: The Small Locking Plate and Screw System is indicated for the clavicle, scapula, olecranon, humerus, radius, ulna, tibia, and fibula. The TDM Screws (1.5mm and larger, Solid and Cannulated) are intended to be used with the plate for internal bone fixation for bone fractures, fusions, osteotomies and non-unions in the foot, hand, wrist, clavicle, scapula, olecranon, humerus, radius, ulna, tibia, and fibula.
Performance Data:	The following testing was performed in accordance with the ASTM F543-17 and ASTM F1264-16: - Static 4-Point Bending - Axial Pullout - Torsional The nonclinical tests and engineering analysis demonstrate that the TDM Plate and Screw Systems is as safe, as effective, and is substantially equivalent to the legally marketed predicate device.
Predicate Device:	Primary predicate: TDM Co. Ltd. – TDM Plate and Screw Systems (K190391). Additional predicate: TDM Co. Ltd. – TDM Plate and Screw Systems (K171808).
Technological Characteristics	The TDM Plate and Screw Systems 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 Plate and Screw Systems 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).