April 5, 2024

Tdm Co., Ltd
% Dave Kim
Regulatory Affairs Cosultant
Mtech Group LLC
7505 Fannin St. Suite 610
Houston, Texas 77054

Re: K232115
Trade/Device Name: TDM Large Bone 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: March 8, 2024
Received: March 8, 2024

Dear Dave Kim:

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)*
K232115

Device Name

TDM Large Bone Plate and Screw System

Indications for Use *(Describe)*

The TopFix System is indicated for the fixation of fractures and osteotomies of the distal femur and proximal tibia related to the treatment of bone and joint deformities and / or malalignment caused by injury or disease (e.g., osteoarthritis).

The Trifix Large System is indicated for the fixation of fractures (including periprosthetic), non-unions, and malunions of the femur and tibia in adult patients with normal or osteopenic bone.

The Newnecks System is indicated for the fixation of fractures of the femoral trochanteric region (e.g., simple intertrochanteric, reverse oblique trochanteric, transverse trochanteric, complex multi-fragmentary, and fractures with associated medial cortex instability).

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"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."

510(k) Summary
K232115

The following 510(k) summary is being submitted as required by 21 CFR Part 807.92;

5.1 **Submitter information**
(21 CFR 807.92(a)(1))

TDM CO., LTD.
69, Cheomdan Venture So-Ro 37beon-Gil
Gwangju, KR 61003
Tel: +82-62-971-7460
Fax: +82-62-971-7461
Establishment registration number: 3014257776

Contact Person:
(Official Correspondent)

Mr. Dave Kim
7505 Fannin St. Suite 610, Houston, TX 77054
Tel: 713-467-2607
Email: davekim@mtechgroupllc.com

Date Prepared: April 3, 2024

Name of the device (21 CFR 807.92(a)(2))

- **Trade Name**
  - TDM Large Bone Plate and Screw System
- **Common Name**
  - Plate, Fixation, Bone (Primary)
  - Screw, Fixation, Bone
- **Classification Name**
  - Single/multiple component metallic bone fixation appliances and accessories (Primary)
  - Smooth or threaded metallic bone fixation fastener
- **Regulation Number**
  - 21 CFR 888.3030 (Primary)
  - 21 CFR 888.3040
- **Regulatory Class**
  - Class II
- **Product Code**
  - HRS (primary)
  - HWC

5.2 **Identification of the predicate (21 CFR 807.92(a)(3))**

- Primary Predicate Device
  - K141796, "DEPUY SYNTHES TOMOFIX OSTEOTOMY SYSTEM", manufactured by "SYNTHES (USA) PRODUCTS LLC"

- Additional Predicate Devices
  - K112406, "PERI-LOC TM Periarticular Lacked Plating System - Proximal Femur Lacking Bone Plate" , manufactured by "Smith & Nephew, Inc."
  - K210043, "LOQTEQ® Distal Lateral Femur Plate 4.5 System", manufactured by "AAP Implantate AG"
  - K080522, "Synthes 3.5 mm LCP Distal Tibia T Plates", manufactured by "Synthes (USA)"

- K202912, "ARIX Ankle Distal Tibia System", manufactured by "Jeil Medical Corporation"
- K213059, "Tibia and Fibula System", manufactured by "Auxein Medical Private Limited"
- K082624, "Synthes (USA) 3.5mm LCP Posteromedial Proximal Tibia PlatesPlates", manufactured by "Synthes (USA)"

- Reference Devices
  - K171808, "TDM Plate and Screw System" manufactured by "TDM Co., Ltd."
  - K190391, "TDM Plate and Screw System" manufactured by "TDM Co. Ltd."

5.3 Description of the device (21 CFR 807.92(a)(4))

The TDM Large Bone Plate and Screw System contains the TopFix System, Trifix Large System, and the Newnecks System, which comprise a family of flat and contoured plates and screws. The plates are constructed from Titanium alloy (Ti-6AL-4V) and come in a variety of configurations. The plates are intended to be used with solid locking and non-locking screws and non-locking low profile screws. The screws are constructed from Titanium alloy (Ti-6AL-4V) and are available as threaded locking screws, cortical or cancellous, cannulated screws from 4.0mm to 6.5mm in diameter and range from 12mm to 100mm in length.

5.4 Statement of intended use (21 CFR 807.92 (a) (5))

The TopFix System is indicated for the fixation of fractures and osteotomies of the distal femur and proximal tibia related to the treatment of bone and joint deformities and / or malalignment caused by injury or disease (e.g., osteoarthritis).

The Trifix Large System is indicated for the fixation of fractures (including periprosthetic), non-unions, and malunions of the femur and tibia in adult patients with normal or osteopenic bone.

The Newnecks System is indicated for the fixation of fractures of the femoral trochanteric region (e.g., simple intertrochanteric, reverse oblique trochanteric, transverse trochanteric, complex multi-fragmentary, and fractures with associated medial cortex instability).

5.5 Summary of technological characteristics (21 CFR 807.92(a)(6))

- **TopFix System**:

The primary predicate device K141796 supports substantial equivalence of the subject Topfix Plates in terms of similar plate designs, similar plate dimensions (i.e., length, width, thickness), similar indications for use (IFU), similar plate materials (Pure Titanium vs Titanium Alloy), sterilization parameters. Comparative mechanical performance testing (per ASTM F382-17) demonstrated greater bending strength and bending structural stiffness compared to the predicate plates (K141796).
The diameters and lengths of the screws for the subject device and the predicate device are similar. They are tested and met the standard specification and test methods as per ASTM F543-17.

- **Trifix Large System**:

The Trifix Large System consists of the following plates: the Distal Femur Locking Plate, Lateral, Distal Tibia Locking Plate, Lateral, Distal Tibia Locking Plate, Medial, Proximal Tibia Locking Plate Lateral, and Proximal Tibia Locking Plate Medial.

- The Distal Femur Locking Plate, Lateral has similar plate material, similar indications for use, plate designs, dimensions, and shape compared to K210043. These plates were evaluated by 4-Point Bend Testing per ASTM F382-17 and found to be substantially equivalent by meeting the mechanical performance criteria set by the FDA Guidance 'Orthopedic Fracture Fixation Plates – Performance Criteria for Safety and Performance Based Pathway'.

- The Distal Tibia Locking Plate, Lateral is similar compared to K080522 in terms of indications for use, plate materials (Titanium Alloy vs Titanium) and design (length, width, shape, thickness). Its mechanical performance demonstrates SE. The plates were evaluated by 4-Point Bend Testing per ASTM F382-17 and found to be substantially equivalent by meeting the mechanical performance criteria set by the FDA Guidance 'Orthopedic Fracture Fixation Plates – Performance Criteria for Safety and Performance Based Pathway'.
- The Distal Tibia Locking Plate, Medial has similar indications for use, plate materials compared to K202912. The plate design and dimension are similar to K202912 demonstrating substantial equivalence. The plates were evaluated by 4-Point Bend Testing per ASTM F382-17 and found to be substantially equivalent by meeting the mechanical performance criteria set by the FDA Guidance 'Orthopedic Fracture Fixation Plates – Performance Criteria for Safety and Performance Based Pathway'.
- The Proximal Tibia Locking Plate Lateral has similar indications for use and plate materials compared to K213059. The plate design and dimension are similar to K213059 demonstrating substantial equivalence. The plates were evaluated by 4-Point Bend Testing per ASTM F382-17 and found to be substantially equivalent by meeting the mechanical performance criteria set by the FDA Guidance 'Orthopedic Fracture Fixation Plates – Performance Criteria for Safety and Performance Based Pathway'.
- The Proximal Tibia Locking Plate Medial compared to K082624 has similar indications and plate materials. The plate design and dimension are similar to K082624 demonstrating substantial equivalence. The plates were evaluated by 4-Point Bend Testing per ASTM F382-17 and found to be substantially equivalent by meeting the mechanical performance criteria set by the FDA Guidance 'Orthopedic Fracture Fixation Plates – Performance Criteria for Safety and Performance Based Pathway'.

- **Newnecks System**:

The Newnecks System consists of the Newnecks plates. The Newnecks plates have similar indications for use and plate materials compared to K112406. The plate design and dimensions are similar to K112406 demonstrating substantial equivalence. These plates were evaluated by 4-Point Bend Testing per ASTM F382-17 and found to be substantially equivalent by meeting the mechanical performance criteria set by the FDA Guidance 'Orthopedic Fracture Fixation Plates – Performance Criteria for Safety and Performance Based Pathway'.

5.6 Brief discussion of non-clinical tests (21 CFR 8070.92(b)(1))

The following properties were tested based on the below referenced standards. The test results support substantial equivalence to the predicate devices.

▪A biocompatibility evaluation for TDM Large Bone Plate and Screw System (subject device) has been conducted. The TDM Large Bone Plate and Screw System is made from Ti6Al4V ELI (ASTM F136) and Pure titanium (ASTM F67), which is the same type of titanium alloy and pure titanium used by the predicate device systems. The assessment results ensures that no additional risks arise from biological hazards associated with materials and, manufacturing methods involved in making the subject device.

▪Performance testing was conducted in conformance to "ASTM F382-17 Standard Specification and Test Method for Metallic Bone Plates" and ASTM F543-17 "Standard Specification and Test Methods for Metallic Medical Bone Screws" and leveraged the FDA Guidance documents "Orthopedic Non-Spinal Metallic Bone Screws and Washers - Performance Criteria for Safety and Performance Based Pathway",

"Orthopedic Fracture Fixation Plates - Performance Criteria for Safety and Performance Based Pathway".

Bench test results concluded that TDM Large Bone Plate and Screw System is substantially equivalent to the predicate devices for its intended use.

5.7 Discussion of clinical tests (21 CFR 807.92(b)(2))

Clinical testing was not required for this submission.

5.8 Conclusion from nonclinical and clinical tests (21 CFR 807.92(a)(3))

The TDM Large Bone Plate and Screw System is substantially equivalent to Predicate Devices. The following comparison table is presented to demonstrate substantial equivalence.

The TDM Large Bone Plate and Screw System does not have a new intended use. It shows equivalent specifications with the predicate devices in most of the parameters. Also, there are no significant differences in some parameters between the TDM Large Bone Plate and Screw System and Predicate Devices.

The TDM Large Bone Plate and Screw System and Predicate Devices has been performed which has resulted in demonstration of similarities in dimensional and performance criteria.

Based on the testing results, TDM CO., LTD. concludes that the subject device is substantially equivalent to the predicate device