November 15, 2019

TDM Co. Ltd.
% Sevrina Ciucci
Regulatory Consultant
Lince Consulting LLC
111 Deerwood Road, Suite 200
San Ramon, California 94583

Re: K190391
Trade/Device Name: TDM Plate and Screw Systems
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: October 16, 2019
Received: October 17, 2019

Dear Sevrina Ciucci:

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,

Shumaya Ali, MPH
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K190391

Device Name
TDM Plate and Screw Systems

Indications for Use *(Describe)*

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) 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.

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510(k) SUMMARY

DATE PREPARED	November 15, 2019
APPLICANT	TDM Co. Ltd. 69, Cheomdan Venture So-ro, 37 beon-gil, Buk-gu, Gwangju, 61003 Republic of Korea Phone: 82-62-971-7460 Fax: 82-62-971-7461 Establishment Registration No.: 3014257776
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ALTERNATE CONTACT	Nancy Lincé Lincé Consulting, LLC Phone: 650-759-6186 Email: nlince@linceconsulting.com
TRADE NAME	TDM Plate and Screw Systems
COMMON NAME	Bone Fixation, Plates and Screws
PRODUCT CODE(S); CFR CLASSIFICATION AND NAME	HRS, HWC 21 CFR§888.3030 Single/multiple component metallic bone fixation appliances and accessories 21 CFR§888.3040 Smooth or threaded metallic bone fixation Fastener
PRIMARY PREDICATE DEVICE	K171808 TDM Plate and Screw System
ADDITIONAL PREDICATE DEVICES	K030310 Synthes Stainless Steel Modular Hand System K050110 Synthes (USA) LCP Modular Foot Plates K060514 Stryker Plating System K061753 Synthes (USA) Clavicle Hook Plate K063049 Synthes (USA) Modular Mini Fragment LCP System K073186 Synthes 3.5mm LCP Clavicle Plate System K082807 Synthes (USA) 3.5mm and 4.5mm Locking Compression Plate (LCP) System with Expanded Indications K083213 Synthes 2.7 mm and 3.5 mm LCP Distal Fibula Plates – Modifications K090047 Synthes (USA) 1.5mm Mini Fragment LCP System

K102694 Synthes 2.4mm Variable Angle LCP Dorsal Distal Radius Plates
K120689 Synthes 3.5 mm VA-LCP Proximal Tibia Plate System
K120854 Synthes Variable Angle LCP Ankle Trauma System
K141735 Arthrex Ankle Fusion Plating System
K150099 DePuy Synthes Variable Angle Locking Hand System (1.3mm and 2.0mm Plates and Screws)
K163293 In2Bones Colink Plating System
K180310 DePuy Synthes Trauma Orthopedic Plates and Screws

DEVICE DESCRIPTION

The TDM Plates 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 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, from 1.5mm to 4.0mm in diameter and range from 6mm to 100mm in length.

INTENDED USE

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) 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.

SUBSTANTIAL EQUIVALENCE SUMMARY

The TDM Plate and Screw System is substantially equivalent to the predicate devices. The basic design features and intended uses are the same. Any differences between the TDM Plate and Screw System and the predicates are considered minor and do not raise questions concerning safety and effectiveness.

The proposed devices are substantially equivalent to the predicate devices in regards to intended use, design, and materials. Performance testing was performed in accordance with ASTM F382-14, “Standard Specification and Test Method for Metallic Bone Plates” and ASTM F543-13, “Standard Specification and Test Methods for Metallic Medical Bone Screws”. The mechanical test data demonstrates that the TDM Plate and Screw System is

adequate for its intended use. LAL bacterial endotoxin testing was conducted. Clinical data was not needed for this device.

Based on the indications for use, technological characteristics, and comparison to the predicate device, the TDM Plate and Screw System is determined to be substantially equivalent to currently marketed predicate devices.