September 13, 2019

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

Re: K190830
Trade/Device Name: TDM Screw Systems
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth Or Threaded Metallic Bone Fixation Fastener
Regulatory Class: Class II
Product Code: HWC
Dated: March 29, 2019
Received: April 1, 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)*
K190830

Device Name
TDM Screw Systems

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 (2.5mm) or small and large bones (4.0mm larger).

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 (2.3mm & 3.5mm, 3.0mm & 4.0mm) and fixation of intra-articular fractures of the humerus, femur and tibia (3.5mm & 5.0mm).

Limited Sliding Screw System:
The Limited Sliding Screw System is intended to be used for fracture fixation of the proximal femur, large bones and large bone fragments.

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

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510(k) SUMMARY

DATE PREPARED	September 9, 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
APPLICATION CORRESPONDENT	Sevrina Ciucci Lincé Consulting, LLC Phone: 408-316-4837 Email: sciucci@linceconsulting.com
ALTERNATE CONTACT	Nancy Lincé Lincé Consulting, LLC Phone: 650-759-6186 Email: nlince@linceconsulting.com
TRADE NAME	TDM Screw Systems
COMMON NAME	Screw, Fixation, Bone Washer, Bolt Nut
PRODUCT CODE(S); CFR CLASSIFICATION AND NAME	HWC; 21 CFR§888.3040 Smooth or threaded metallic bone fixation Fastener HTN; 21 CFR§888.3030 Single/multiple component metallic bone fixation appliances and accessories
PRIMARY PREDICATE DEVICES	K161616 Synthes Cannulated, Cortex, and Headless Compression Screws
ADDITIONAL PREDICATE DEVICES	K123890 Acumed Cannulated Screw System K021556 Synthes 2.4mm Cannulated Compression Screw K050636 Synthes 3.0mm Headless Compression Screws K080943 Synthes 4.5 mm and 6.5 mm Headless Compression Screws K063020 INTAI Bone Screw System
DEVICE 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 120mm. The Washer is available in 5.5mm to 13mm. The Screws are intended for standalone use.

INTENDED 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 (2.5mm) or small and large bones (4.0mm larger).

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 (2.3mm & 3.5mm, 3.0mm & 4.0mm) and fixation of intra-articular fractures of the humerus, femur and tibia (3.5mm & 5.0mm).

Limited Sliding Screw System:
The Limited Sliding Screw System is intended to be used for fracture fixation of the proximal femur, large bones and large bone fragments.

COMPARISON TO PREDICATE INDICATIONS

The subject TDM Screw Systems and the predicate systems are intended to be used for fixation of fractures, fusions, osteotomies, non-unions, and malunions of bones appropriate for the size of the device. All indications for the subject device are within the indications of the predicate devices.

COMPARISON TO PREDICATE TECHNOLOGICAL CHARACTERISTICS

The components of the TDM Screw Systems possess the same technological characteristics as the predicate devices and these include:

- performance,
- basic design,
- material, manufacturing, and
- sizes (dimensions are comparable to those offered by the predicate systems).

Differences between the TDM Screw Systems and the predicate devices are considered minor and were not shown to raise new questions concerning safety and effectiveness.

SUMMARY OF NON-CLINICAL TESTING

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 F543-17, “Standard Specification and Test Methods for Metallic Medical Bone Screws”. ASTM F1264-16 “Standard Specification and Test Methods for Intramedullary Fixation Devices” served as

a guideline for the methods of screw three-point bend testing. The mechanical test data demonstrates that the TDM Screw Systems are adequate for their intended use. LAL bacterial endotoxin testing was conducted. Clinical data was not needed for this device.

CONCLUSION

Based on the indications for use, technological characteristics, performance testing, and comparison to the predicate devices, the TDM Screw Systems are substantially equivalent to currently marketed predicate devices.

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

March 15, 2018

Re: K171808
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: February 5, 2018
Received: February 6, 2018

Dear Babu Periasamy:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820);

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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K171808

Device Name
TDM Plate and Screw System

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, calcaneous, fibula and other small bones.

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, calcaneous, femur 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)

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PRAStaff@fda.hhs.gov

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510(k) SUMMARY

DATE PREPARED	June 16, 2017
APPLICANT	TDM Co. Ltd. #F105-1.101-104, Sangsan-dong,333, Cheonmdangwagi-ro, Buk-gu, Gwangju, 61008, Republic of Korea Phone: 82-62-602-7460 Fax: 82-62-602-7461
OFFICIAL CORRESPONDENT	Sevrina Ciucci Lincé Consulting, LLC Phone: 408-316-4837 Email: sciucci@linceconsulting.com
ALTERNATE CONTACT	Nancy Lincé Lincé Consulting, LLC Phone: 650-759-6186 Email: nlince@linceconsulting.com
TRADE NAME	TDM Plate and Screw System
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
PREDICATE DEVICE(S)	Arthrex Fracture Plates (K123241 (subsequently cleared under K141478 & K151732) Arthrex Ankle Fusion Plating System (K141735) Biomet A.L.P.S Calcaneal Plating System (K132898) Hand Innovations Distal Radius Fracture Repair Kit (K030198) Synthes Calcaneal Plate (K020401) Synthes (USA) Clavicle Hook Plate (K061753) Synthes (USA) 1.5mm Mini Fragment LCP System (K090047)
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 70mm 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, calcaneous, fibula and other small bones.

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, calcaneous, femur 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.