



April 8, 2024

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

Re: K240423

Trade/Device Name: TDM Anterior Cervical Plate System
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal Intervertebral Body Fixation Orthosis
Regulatory Class: Class II
Product Code: KWQ
Dated: February 9, 2024
Received: February 13, 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.

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,

Colin
O'Neill -S 

Colin O'Neill, M.B.E.

Assistant Director

DHT6B: Division of Spinal Devices

OHT6: Office of Orthopedic Devices

Office of Product Evaluation and Quality

Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K240423

Device Name

TDM Anterior Cervical Plate System

Indications for Use (Describe)

The TDM Anterior Cervical Plate System is intended for anterior fixation of the cervical spine (C2 to C7). The system is to be used to provide stabilization of the anterior cervical spine as an adjunct to fusion for the treatment of degenerative disc disease (DDD) (defined as neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, trauma (i.e., fracture or dislocation), spinal stenosis, deformities or curvatures (i.e., scoliosis, kyphosis, and/or lordosis), tumor, pseudoarthrosis, and failed previous fusion.

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

TDM's
TDM Anterior Cervical Plate System

Sponsor:	Manufacturer TDM Co. Ltd. 69, Cheomdan Venture So-ro, 37 beon-gil, Buk-gu Gwangju, 61003, Republic of Korea Official Contact Jungwook Choi Phone: +82-62-971-7460 Fax: +82-62-971-7461 Contact Person Jeena Mathai mgsharemg@gmail.com Date: March 30, 2024
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Device Name:	TDM Anterior Cervical Plate System
Common Name:	Anterior Cervical Plate System
Classification Name:	Spinal Intervertebral Body Fixation Orthosis
Classification Number:	21 CFR 888.3060
Product Code/Classification:	KWQ, class II

Description:	The TDM Anterior Cervical Plate System consists of cervical plates, screws and the instruments necessary to implant this specific system. All implant components are made from a titanium alloy (Ti-6AL-4V). The fixation construct consists of a cervical plate that is attached to the vertebral body of the cervical spine with self-tapping and self-drilling bone screws using an anterior approach. Cervical Plate System is provided as non-sterile. The implants are intended for single-use only, while the instruments are reusable.
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Indications For Use:	The TDM Anterior Cervical Plate System is intended for anterior fixation of the cervical spine (C2 to C7). The system is to be used to provide stabilization of the anterior cervical spine as an adjunct to fusion for the treatment of degenerative disc disease (DDD) (defined as neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, trauma (i.e., fracture or dislocation), spinal stenosis, deformities or
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curvatures (i.e., scoliosis, kyphosis, and/or lordosis), tumor, pseudoarthrosis, and failed previous fusion.

Performance Data:	Non-clinical testing was performed to demonstrate that the subject TDM Anterior Cervical Plate System is substantially equivalent to the predicate device. The following testing was performed in accordance with ASTM F1717: - Static compression - Dynamic compression - Static Torsion
Primary Predicate Device:	Synthes Spine - Synthes Anterior CSLP System (K000742)
Reference Devices:	K171808 & K190391 - TDM Plate and Screw System
Technological Characteristics:	The TDM Anterior Cervical Plate System has substantially equivalent technological characteristics to its predicate and reference devices through comparison in areas including design, labeling/intended use, material composition, function, range of sizes, and packaging.
Conclusion:	The TDM Anterior Cervical Plate 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).