Tdm Co., Ltd.
℅ Dave Kim
Medical Regulatory Affairs
Mtech Group
7505 Fannin St. Suite 610
Houston, Texas 77054

August 22, 2024

Re: K230071
Trade/Device Name: Femur Reconstruction Interlocking Nail System, Femur Retrograde Interlocking Nail System, Humerus Interlocking Nail System, Tibia Interlocking Nail System, Compression Hip Nail System
Regulation Number: 21 CFR 888.3020
Regulation Name: Intramedullary fixation rod
Regulatory Class: Class II
Product Code: HSB
Dated: August 15, 2024
Received: August 15, 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,

Farzana Sharmin -S

Digitally signed by Farzana Sharmin -S
Date: 2024.08.22 14:16:28 -04'00'

Farzana Sharmin, PhD
Assistant Director
DHT6A: Division of Joint Arthroplasty Devices
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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)*
K230071

Device Name
Femur Reconstruction Interlocking Nail System, Femur Retrograde Interlocking Nail System, Humerus Interlocking Nail System, Tibia Interlocking Nail System, Compression Hip Nail System

Indications for Use *(Describe)*

(1) Femur Reconstruction Interlocking Nail System
The Femur Reconstruction Interlocking Nail System is intended to stabilize femoral shaft fractures, subtrochanteric fractures, ipsilateral neck/shaft fractures, impending pathologic fractures, non-unions and malunions.

(2) Femur Retrograde Interlocking Nail System
The Femur Retrograde Interlocking Nail System is indicated for simple long bone fractures; severely comminuted, spiral, large oblique and segmental fractures; nonunions and malunions; polytrauma and multiple fractures; prophylactic nailing of impending pathologic fractures; reconstruction, following tumor resection and grafting; supracondylar fractures; bone lengthening and shortening. Interlocking intramedullary nails are indicated for fixation of fractures that occur in and between the proximal and distal third of long bones being treated.

(3) Humerus Interlocking Nail System
The Humerus Interlocking Nail System indicated for fractures of the proximal humerus, including 2-part surgical neck fractures, 3-part fractures, and 4-part fractures, proximal humeral fractures with diaphyseal extension, diaphyseal fractures of the humeral shaft, and impending pathologic humeral fractures.

(4) Tibia Interlocking Nail System
The Tibia Interlocking Nail System is intended to stabilize fractures of the proximal and distal tibia and the tibial shaft; open and closed tibial shaft fractures; certain pre- and post-isthmic fractures; and tibial malunions and non- unions.

(5) Compression Hip Nail System
The Compression Hip Nail System is intended to treat stable and unstable proximal femoral fracture including Pertrochanteric fractures, Intertrochanteric fractures and High sub trochanteric fractures and combination of these fractures.

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.

510(k) Summary
K230071

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

5.1 Submitter:

TDM CO., LTD.
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Gwangju, KR 61003
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Establishment registration number: 3014257776

Contact Person: Mr. Dave Kim
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Date Prepared: 01/25/2024

5.2 Device Identification

Device Trade Name	Femur Reconstruction Interlocking Nail System, Femur Retrograde Interlocking Nail System, Humerus Interlocking Nail System, Tibia Interlocking Nail System, Compression Hip Nail System
Common Name	Intramedullary Fixation Nailing System
Classification Name	Intramedullary Fixation Rod
(Regulation Number)	(21 CFR 888.3020)
Device Classification	II
Product Code	HSB

5.3 Predicate and Reference devices:

Predicate device: K192003, "Auxein Nailing System", manufactured by "Auxein Medical Private Limited"
Reference device #01: K120807, "Synthes Multiloc Humeral Nailing System", manufactured by "Synthes"
Reference device #02: K040762, "Synthes(USA) Tibial Nail System EX", manufactured by "Synthes"
Reference device #03: K200869, "Gamma3 System Lag Screws", manufactured by "Stryker Trauma GmbH"
Reference device #04: K200880, "T2 Femur Nail", manufactured by "Stryker GmbH"

5.4 Device Description

This intramedullary fixation rod is used for stabilization of shaft fracture in humeral bone, femoral bone and tibial bone. It is implanted into medullary cavity inside of the long bone (humeral bone, femoral bone and tibial bone) with a fracture and the fractured long bone (humeral bone, femoral bone and tibial bone) is fixed to the nail by using the locking screw at the upper and lower parts of the fractured part.

The nailing system consists of the Femur Reconstruction Interlock Nail System, Femur Retrograde Interlocking Nail System, Humerus Interlocking Nail System, Tibia Interlocking Nail System, and Compression Hip Nailing System.

- **Indications for use**
  - Femur Reconstruction Interlocking Nail System
    The Femur Reconstruction Interlocking Nail System is intended to stabilize femoral shaft fractures, subtrochanteric fractures, ipsilateral neck/shaft fractures, impending pathologic fractures, non-unions and malunions.

  - Femur Retrograde Interlocking Nail System
    The Femur Retrograde Interlocking Nail System is indicated for simple long bone fractures; severely comminuted, spiral, large oblique and segmental fractures; nonunions and malunions; polytrauma and multiple fractures; prophylactic nailing of impending pathologic fractures; reconstruction, following tumor resection and grafting; supracondylar fractures; bone lengthening and shortening. Interlocking intramedullary nails are indicated for fixation of fractures that occur in and between the proximal and distal third of long bones being treated.

  - Humerus Interlocking Nail System
    The Humerus Interlocking Nail System indicated for fractures of the proximal humerus, including 2-part surgical neck fractures, 3-part fractures, and 4-part fractures, proximal humeral fractures with diaphyseal extension, diaphyseal fractures of the humeral shaft, and impending pathologic humeral fractures.

  - Tibia Interlocking Nail System
    The Tibia Interlocking Nail System is intended to stabilize fractures of the proximal and distal tibia and the tibial shaft; open and closed tibial shaft fractures; certain pre- and post-isthmic fractures; and tibial malunions and non- unions.

  - Compression Hip Nail System
    The Compression Hip Nail System is intended to treat stable and unstable proximal femoral fracture including Pertrochanteric fractures, Intertrochanteric fractures and High sub trochanteric fractures and combination of these fractures.

- **Non-clinical Test Conclusion**
  The following properties were tested based on the referenced standards. All the test results support substantial equivalence to the predicate devices.

  - ISO 10993-3- Genotocixity (Bacterial reverse mutation) & Genotocixity (chromosomal aberration)

- ISO 10993-5- Cytotoxicity
- ISO 10993-6- Implantation
- ISO 10993-10 – Skin Sensitization & Intracutatneous Reactivity
- ISO 10993-11 – Acute systemic toxicity & Subchronic Toxicity & Pyrogens
- testing per ASTM F1264, ASTM F543, and ASTM F384

- **Clinical Test Conclusion**
  Clinical testing was not required for this submission.

- **Technical Characteristics and Substantial Equivalence**

The subject device is substantially equivalent to "Auxein Nailing System (K192003)", the predicate device, based on the following:

- The subject device does not have a new intended use. It shows equivalent specifications with the predicate device in most of the parameters.
- The subject device is intramedullary fixation nailing system which employs Femur Reconstruction Interlocking Nail, Femur Retrograde Interlocking Nail System Humerus Interlocking Nail Tibia Interlocking Nail System, and Compression Hip Nail System, designed similar to the predicate device.
- Both the subject device and the predicate device are made of titanium alloy.
- The nails, lag screws and supplemental screws are in the similar range of lengths and diameters as the predicate device.

6. Conclusion:

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