December 21, 2022

Double Medical Technology Inc.
Yan Zuo
Deputy International RA Supervisor
No.18, Shanbianhong East Road, Haicang District
Xiamen, Fujian 361026
China

Re: K221221
Trade/Device Name: Advanced Intramedullary Nail System
Regulation Number: 21 CFR 888.3020
Regulation Name: Intramedullary Fixation Rod
Regulatory Class: Class II
Product Code: HSB
Dated: December 9, 2022
Received: December 19, 2022

Dear Yan Zuo:

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,

Victoria A. Lilling -S

Digitally signed by Victoria A. Lilling -S
Date: 2022.12.21 15:47:49 -05'00'

Victoria Lilling, M.D.
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)*
K221221

Device Name
Advanced Intramedullary Nail System

Indications for Use *(Describe)*
Advanced Intramedullary Nail System is intended to be implanted into the medullary canal of limbs for alignment, stabilization, fixation of fractures caused by trauma or diseases.
Indications:
1.Ulna Nail: Indicated for the fixation of fractures and osteotomies of the ulna.
2.Fibular Nail: Indicated for fixation of fractures and osteotomies of the fibula.
3.Ankle Fusion Nail: Indicated for degeneration,deformity, or trauma of both the tibiotalar and talocalcaneal articulations in the hindfoot: tibiocalcaneal arthrodesis; combined arthrodesis of the ankle and subtalar joints; avascular necrosis of the ankle and subtalar joints; failed total ankle replacement with subtalar intrusion;failed ankle arthrodesis with insufficient talar body; rheumatoid arthritis; severe deformity secondary to untreated talipes equinovarus or neuromuscular disease; and severe pilon fractures with trauma to the subtalar joints.

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.

K221221- 510(k) Summary

1. Submitter	
Name	Double Medical Technology Inc.
Address	No. 18, Shanbianhong East Road, Haicang District, Xiamen, 361026, P. R. China
Phone	+86 592 6885079
Fax	+86 592 6587078
Contact person	Yan Zuo
Date prepared	December 21th, 2022
2. Proposed Device	
Trade/proprietary name	Advanced Intramedullary Nail System
Common or usual name	Advanced Intramedullary Nail System
Classification name	Intramedullary fixation rod
Regulation number	21 CFR 888.3020
Product code	HSB
Regulatory class	II
Classification panel	Orthopedic
3. Predicate Device	
Legally marketed device(s) to which equivalence is claimed	**Primary predicate device:** K143276 Acumed Small Bone IM Nail System **Additional predicate devices:** K043052 TriGen Hindfoot Fusion Nail
Reason for 510(k) submission	New device (Implant)

4. Device Description

The method of intramedullary nail fixation is symmetrical central splint fixation; central fixati on is theoretically superior to cortical external fixation, which can reduce the moment arm, re duce the incidence of varus and valgus angulation and internal fixation failure. Intramedullary nail fixation of fractures is stress-distributed fixation rather than stress-shielded fixation, whi ch is beneficial to the plasticity of callus. Advanced Intramedullary Nail System are made of Ti-6Al-4V ELI following ASTM F136. Advanced Intramedullary Nail System is provided as non-sterile. The implants are intended for single-use only, while the instruments are reusable.

5. Indication for Use

Advanced Intramedullary Nail System is intended to be implanted into the medullary canal of limbs for alignment, stabilization, fixation of fractures caused by trauma or diseases.

Indications:

(1) Ulna Nail: Indicated for the fixation of fractures and osteotomies of the ulna.

(2) Fibular Nail: Indicated for fixation of fractures and osteotomies of the fibula.

(3) Ankle Fusion Nail: Indicated for degeneration,deformity, or trauma of both the tibiotalar and talocalcaneal articulations in the hindfoot;tibiocalcaneal arthrodesis; combined arthrodesis of the ankle and subtalar joints; avascular necrosis of the ankle and subtalar joints; failed total ankle replacement with subtalar intrusion;failed ankle arthrodesis with insufficient talar body; rheumatoid arthritis; severe deformity secondary to untreated talipes equinovarus or neuromuscular disease; and severe pilon fractures with trauma to the subtalar joints.

6. Comparison of Technological Characteristics with the Predicate Device

The rationale for substantial equivalence is based on consideration of the following characteristics:

Regulatory Classification: Same as the predicate devices

Indications for Use: Substantially equivalent (SE) to the predicate devices

Materials: Substantially equivalent (SE) to the predicate devices

Design Features: Substantially equivalent (SE) to the predicate devices

7. Non-Clinical Performance Data

7.1 Biocompatibility testing

The biocompatibility evaluation for the Advanced Intramedullary Nail System was conducted in accordance with the FDA Guidance “Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process".

7.2 Mechanical testing

The following tests were performed (per ASTM F543-17 *Standard Specification and Test Methods for Metallic Medical Bone Screws* and ASTM F1264-16 *Standard Specification and Test Methods for Intramedullary Fixation Devices)* on Advanced Intramedullary Nail System to demonstrate substantially equivalent of safety and efficacy with the predicate device:

Locking Screw:

- Torsion Test

- Insertion/removal Test
- Self-tapping Test
- Pullout Test
- Bending Test

Intramedullary Nail:

- Four-Point Bend Test
- Static Torsion Test

8. Clinical Data

No clinical performance data was provided to demonstrate substantially equivalence.

9. Conclusion

Advanced Intramedullary Nail System does not raise different questions of safety and effectiveness when compared to the predicate device. The information provided within this premarket notification demonstrates that proposed device is determined to be substantially equivalent (SE) to the predicate device.