January 25, 2023

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

Re: K221150
Trade/Device Name: Advanced Bone Plate
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: November 22, 2022
Received: November 29, 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,

Shumaya Ali -S

Shumaya Ali, M.P.H.
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K221150

Device Name
Advanced Bone Plate

Indications for Use *(Describe)*
Indications for use:

The Advanced Bone Plate (AIMIMINI VARIABLE ANGLE LOCKING PLATES SYSTEM, ITVAL Foot & Ankle VAL System, and Distal Fibular VAL Plate) is indicated for internal fixation. Specific indications for the plates included in the system as follows:

The AIMIMINI VARIABLE ANGLE LOCKING PLATES SYSTEM is indicated for the internal fixation (fractures, osteotomies, arthrodesis, replantations and reconstructions) of the hand (metacarpals and phalanges) and wrist of adults and adolescents (age 12-21 years) in which growth plates have fused or will not be crossed by fixation.

The ITVAL Foot & Ankle VAL System is indicated for internal fixation (fractures, osteotomies, fusions, nonunions, malunions, small fragment replantations) of the foot and ankle in adults and adolescents (age 12-21 years) possessing normal or osteopenic bone where growth plates have fused or will not be crossed by fixation.

The Distal Fibular VAL Plate is indicated for internal fixation (fractures, osteotomies, nonunions, malunions, small fragment replantations) of the distal fibula of adults and adolescents (age 12-21 years) where growth plates have fused or will not be crossed by fixation.

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.

K221150 - 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
Contact person	Yan Zuo
Date prepared	Jan 20th, 2023
2. Proposed Device	
Trade/proprietary name	Advanced Bone Plate
Common or usual name	Plate, Fixation, Bone; Screw, Fixation, Bone
Classification name	Single/multiple component metallic bone fixation appliances and accessories (Primary); Smooth or threaded metallic bone fixation fastener
Regulation number	21 CFR 888.3030 (Primary); 21 CFR 888.3040
Product code	HRS; HWC
Regulatory class	II
Classification panel	Orthopedic
3. Predicate Device	

Legally marketed device(s) to which equivalence is claimed	**Primary predicate device:** K141527 DePuy Synthes Variable Angle Locking Hand System **Additional predicate devices:** K103243 Synthes (USA) 2.4mm VA-LCP Intercarpal Fusion System K152974 Wright ORTHOLOC®3Di Foot Reconstruction System K090692 Wright ORTHOLOC® 2.0/ 2.4 Plate System K171852 Wright DARCOTM Locking Bone Plate System K142121 Wright ORTHOLOC® Calcaneal Plating System K130108 Double Engine Bone Plate and Bone Screw System K141383 Acumed Hand Plating System K151277 NOVASTEP Airlock® osteosynthesis plate system K222194 Baby Gorilla®/Gorilla® Plating System K132898 Biomet A.L.P.S. Calcaneal Plating System K132886 Smith&Nephew Variable- Angle Locking
Reason for 510(k) submission	New device(Implant)

4. Device Description

Advanced Bone Plate is mainly used for internal fixation of hand, wrist, foot, ankle and distal fibular fractures. According to the anatomical characteristics of human bones, locking plates of different shapes and locking screws of different diameters are designed. In clinical practice, locking bone plate and locking bone screw are used in combination to play the role of temporary internal stent, providing a stable local environment for fracture ends and creating conditions for the healing of fracture ends.

Bone plates in Advanced Bone Plate are made of titanium alloy following ASTM F1472, and bone screws in Advanced Bone Plate are made of titanium alloy following ASTM F136.

Advanced Bone Plate is provided as non-sterile. The implants are intended for single-use only, while the instruments are reusable.

5. Indications for Use

The Advanced Bone Plate (AIMIMINI VARIABLE ANGLE LOCKING PLATES SYSTEM, ITVAL Foot & Ankle VAL System, and Distal Fibular VAL Plate) is indicated for internal fixation. Specific indications for the plates included in the system as follows:

The AIMIMINI VARIABLE ANGLE LOCKING PLATES SYSTEM is indicated for the internal fixation (fractures, osteotomies, arthrodesis, replantations and reconstructions) of the hand (metacarpals and phalanges) and wrist of adults and adolescents (age 12-21 years) in which growth plates have fused or will not be crossed by fixation.

The ITVAL Foot & Ankle VAL System is indicated for internal fixation (fractures, osteotomies, fusions, nonunions, malunions, small fragment replantations) of the foot and ankle in adults and adolescents (age 12-21 years) possessing normal or osteopenic bone where growth plates have fused or will not be crossed by fixation.

The Distal Fibular VAL Plate is indicated for internal fixation (fractures, osteotomies, nonunions, malunions, small fragment replantations) of the distal fibula of adults and adolescents (age 12-21 years) where growth plates have fused or will not be crossed by fixation.

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: Bone plates in Advanced Bone Plate are made of titanium alloy following ASTM F1472, and bone screws in Advanced Bone Plate are made of titanium alloy following ASTM F136. Both of the materials of bone plates and bone screws are substantially equivalent (SE) to the predicate devices.

Design Features: The subject Advanced Bone Plate shares the same fundamental technological characteristics as the predicate systems. The same design features of the subject and predicate systems such as variable angle locking technology, limited contact profiles, anatomic contours, and similar size ranges. Based on the presented comparisons and discussions, the subject Advanced Bone Plate does not raise any new issues of safety and efficacy.

7. Non-Clinical Performance Data

7.1 Biocompatibility testing

The biocompatibility evaluation for the Advanced Bone Plate 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 mechanical tests of bone plates were performed per *ASTM F382-17 Standard Specification and Test Methods for Metallic bone plate* and Three-point Bending Test Method to demonstrate substantially equivalent of safety and efficacy with the predicate device. According to ASTM F382-17 and Three-point Bending Test Method, test methods are used to determine the Bending Stiffness, Bending Strength and Bending Structural Stiffness.

The mechanical tests of bone screws were performed per *ASTM F543-17 Standard Specification and Test Methods for Metallic Medical Bone Screws* to demonstrate substantially equivalent of safety and efficacy with the predicate device. According to *ASTM* F543-17, test methods are used to determine the Torsion Test, Insertion/removal Test and Pullout Test.

7.3 Sterilization & Reprocessing

The Advanced Bone Plate is provided as non-sterile. It required to be sterilized via Overkill Approach (Half-Cycle method) to reach a SAL of 10^{-6} by the hospital prior to surgery. The sterilization method is presented in the instruction for use, which was validated per *ISO 17665-1: 2006 Sterilization of health care products - Moist heat - Part 1: Requirements for the development, validation, and routine control of a sterilization process for medical devices.*

Implants and instruments must be carefully cleaned before initial sterilization. The cleaning instructions presented in the instruction for use have been validated per FDA guidance *AAMI TIR30:2003 "A compendium of processes, materials, test methods, and acceptance criteria for cleaning reusable medical devices.*

8. Clinical Data

No clinical performance data was provided to demonstrate substantially equivalence.

9. Conclusion

Advanced Bone Plate is compared to the predicate devices in respect of safety and effectiveness. The information provided within this premarket notification demonstrates that proposed device is determined to be substantially equivalent (SE) to the predicate device.