January 18, 2023

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

Re: K221088
Trade/Device Name: Anatomic 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
Dated: September 16, 2022
Received: September 23, 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)*
K221088

Device Name
Anatomic Bone Plate

Indications for Use *(Describe)*

The Anatomic Bone Plates are intended for the internal fixation of fractures (VAL Distal Clavicle, VAL Proximal Humeral, VAL Distal Humeral, Distal Ulnar Locking, Distal Radial Locking, VAL Proximal Tibia, VAL Distal Tibia, VAL Distal Lateral Fibular, VAL Distal Femoral, Pelvic Bone Plate), fracture dislocations (VAL Proximal Humeral), osteotomies, and mal/non-unions (VAL Distal Clavicle, VAL Proximal Humeral, VAL Distal Humeral) of the clavicle, pelvis, and the upper (i.e., humerus, ulna and radius) and lower (i.e., femur, tibia, and fibula) extremities. Additional plates included in the system with specific indications as follows:

VAL (Variable Angle Locking) Distal Clavicle Plate is indicated for fractures of the shaft and lateral clavicle, malunions and non-unions ;
VAL Distal Humeral Plate is indicated for fractures (including supracondylar), and nonunions ;
VAL Distal Femoral Plate is indicated for distal femoral fractures (diaphyseal, supracondylar, , and intra-articular);
Pelvic Bone Plate is indicated for pelvic fractures (e.g., acetabular , iliac wing, and symphysis pubis).

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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K221088 - 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 16th, 2023
2. Proposed Device	
Trade/proprietary name	Anatomic Bone Plate
Common or usual name	Anatomic Bone Plate
Classification name	Single/multiple component metallic bone fixation appliances and accessories
Regulation number	21 CFR 888.3030
Product code	HRS
Regulatory class	II
Classification panel	Orthopedic
3. Predicate Device	
Legally marketed device(s) to which equivalence is claimed	**Predicate device:** K130108 Double Engine Bone Plate and Bone Screw System
Reason for 510(k) submission	New device

4. Device Description

Anatomic Bone Plate is mainly used for internal fixation of fracture. 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. Anatomic Bone Plate is provided as non-sterile. The implants are intended for single-use only, while the instruments are reusable.

Anatomic Bone Plate are made of titanium alloy following ASTM F1472 or unalloyed titanium following ASTM F67.

5. Indications for Use

The Anatomic Bone Plates are intended for the internal fixation of fractures (VAL Distal Clavicle, VAL Proximal Humeral, VAL Distal Humeral, Distal Ulnar Locking, Distal Radial Locking, VAL Proximal Tibia, VAL Distal Tibia, VAL Distal Lateral Fibular, VAL Distal Femoral, Pelvic Bone Plate), fracture dislocations (VAL Proximal Humeral), osteotomies, and mal/non-unions (VAL Distal Clavicle, VAL Proximal Humeral, VAL Distal Humeral) of the clavicle, pelvis, and the upper (i.e., humerus, ulna and radius) and lower (i.e., femur, tibia, and fibula) extremities. Additional plates included in the system with specific indications as follows:

- VAL (Variable Angle Locking) Distal Clavicle Plate is indicated for fractures of the shaft and lateral clavicle, malunions and non-unions ;
- VAL Distal Humeral Plate is indicated for fractures (including supracondylar), and nonunions ;
- VAL Distal Femoral Plate is indicated for distal femoral fractures (diaphyseal, supracondylar, and intra-articular);
- Pelvic Bone Plate is indicated for pelvic fractures (e.g., acetabular , iliac wing, and symphysis pubis).

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 Anatomic 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 were performed per *ASTM F382-17 Standard Specification and Test Methods for Metallic bone plate* and three-point bending test method on Anatomic Bone Plate 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.

8. Clinical Data

Clinical literature was provided to demonstrate substantially equivalence.

9. Conclusion

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