December 12, 2022

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

Re: K220921
Trade/Device Name: Metal Bone Screw
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth Or Threaded Metallic Bone Fixation Fastener
Regulatory Class: Class II
Product Code: HWC
Dated: November 9, 2022
Received: November 14, 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)*
K220921

Device Name
Metal Bone Screw

Indications for Use *(Describe)*
Metal Bone Screw is indicated for the fixation of clavicle, scapula, pelvis, humerus, ulna, radius, femur, tibia, fibula, metacarpals, metatarsals and phalanges 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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K220921 - 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 8th, 2022
2. Proposed Device	
Trade/proprietary name	Metal Bone Screw
Common or usual name	Metal Bone Screw
Classification name	Smooth or threaded metallic bone fixation fastener.
Regulation number	21 CFR 888.3040
Product code	HWC
Regulatory class	II
Classification panel	Orthopedic
3. Predicate Device	
Legally marketed device(s) to which equivalence is claimed	**Primary predicate device:** K130108 Double Engine Bone Plate and Bone Screw System **Additional predicate device:** K143146 Nexis® osteosynthesis snap-off screws
Reason for 510(k) submission	New device(Implant)

4. Device Description

Metal Bone Screw are used to fasten plates onto bones, or, as lag screws, to hold bone fragments together. The screws are differentiated by the manner in which they are inserted into bone, their function, their size, and the type of bone they are intended for. Metal Bone Screw consists of a series of screws with different sizes and structures, which is designed according to the anatomical characteristics of human bones. In clinical practice, the bone screw can be used alone or in combination with the bone plate, which acts as a temporary internal support, provides a stable local environment for the fractured end, and creates conditions for the healing of the fractured end. Metal Bone Screw are made of Ti-6Al-4V ELI following ASTM F136. Metal Bone Screw is provided as non-sterile. The implants are

intended for single-use only, while the instruments are reusable.

5. Indication for Use

Metal Bone Screw is indicated for the fixation of clavicle, scapula, pelvis, humerus, ulna, radius, femur, tibia, fibula, metacarpals, metatarsals and phalanges fractures.

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 Metal Bone Screw 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.)* on Metal Bone Screw to demonstrate substantially equivalent of safety and efficacy with the predicate device:

- Torsion Test
- Insertion/removal Test
- Pullout Test

8. Clinical Data

No clinical performance data was provided to demonstrate substantially equivalence.

9. Conclusion

Metal Bone Screw 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.