



December 4, 2024

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

Re: K242348

Trade/Device Name: Locking Screw,CoCrMo
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth Or Threaded Metallic Bone Fixation Fastener
Regulatory Class: Class II
Product Code: HWC, HRS
Dated: November 8, 2024
Received: November 8, 2024

Dear Joy 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 (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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at <https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system>.

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,

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

Indications for Use

Submission Number (if known)

K242348

Device Name

Locking Screw,CoCrMo

Indications for Use (Describe)

Locking Screw,CoCrMo 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.

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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	Agu. 1st, 2024
2. Proposed Device	
Trade/proprietary name	Locking Screw, CoCrMo
Common or usual name	Smooth or threaded metallic bone fixation fastener, Single/multiple component metallic bone fixation appliances and accessories
Classification name	Bone, Fixation, Screw; Bone, Fixation, Plate
Regulation number	21 CFR 888.3040 (primary), 21 CFR 888.3030
Product code	HWC (primary), HRS
Regulatory class	II
Classification panel	Orthopedic
3. Predicate Device	
Legally marketed device(s) to which equivalence is claimed	Primary predicate device: K220921 Double Medical Metal Bone Screw Additional predicate device: K221088 Double Medical Anatomic Bone Plate K130108 Double Engine Bone Plate and Bone Screw Systems K221150 Advanced Bone Plate
Reason for 510(k) submission	New device(Implant)

4. Device Description

Locking Screw, CoCrMo is 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. Locking Screw, CoCrMo 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 shall be used 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. Locking Screw,CoCrMo is made of CoCrMo following ASTM F1537. Locking Screw,CoCrMo is provided as sterile and non-sterile. The implants are intended for single-use only.

5. Indication for Use

Locking Screw,CoCrMo 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 Locking Screw,CoCrMo 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 Locking Screw,CoCrMo 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 substantial equivalence.

9. Conclusion

Locking Screw,CoCrMo 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.