January 10, 2023

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

Re: K221090
Trade/Device Name: Metal Cannulated Screw
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth Or Threaded Metallic Bone Fixation Fastener
Regulatory Class: Class II
Product Code: HWC
Dated: October 14, 2022
Received: October 18, 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)*
K221090

Device Name
Metal Cannulated Screw

Indications for Use *(Describe)*
Metal Cannulated Screw is indicated for internal fixation of fracture, fusion and correction of limb bone and metaphysis, hand and foot:
1)The 2.3mm No Profile Cannulated Screw is indicated for the fixing and stabilizing the elective osteotomies of the mid foot bones and the metatarsal and phalanges of the foot only.
2)The 3.0mm No Profile Cannulated Screw is indicated for internal fixation of bone fractures of ulna, radius, fibula, and small bones (metacarpals, metatarsals, and phalanges).
3)The 4.0mm No Profile Cannulated Screw and 4.0mm No Profile Cannulated Screw, Oblique are indicated for fixation of fractures, fusions, osteotomies, non-unions, and malunions of small bones and small bone fragments.
4)The 5.0mm No Profile Cannulated Screw and 5.0mm No Profile Cannulated Screw, Oblique are indicated for fixation of fractures, fusions, osteotomies, non-unions, and malunions of long bones and long bone fragments, and the bones of the hand and foot.
5)The 7.0mm No Profile Cannulated Screw and 7.0mm No Profile Cannulated Screw, Oblique are indicated for fixation of fractures, fusions, osteotomies, non-unions, and malunions of long bones and long bone fragments, pelvis, sacrum, and the bones of the foot. These screws are also indicated for femoral neck fractures, slipped capital femoral epiphysis, an adjunct to DHS (Dynamic Hip System) in basilar neck fractures, tibial plateau fractures, ankle arthrodesis, intercondylar femur fractures, SI joint disruptions and subtalar arthrodesis.
6)The Headless Cannulated Screw (2.5-4.5mm) /Headless Compression Screw (2.5-4.5mm) are indicated for fixation of fractures in large bones of humerus, ulna, radius, tibia and fibula, and small bones of the foot. These screws are also indicated for intra-articular fractures of knee and ankle joint.
7)The Headless Cannulated Screw (5.0-7.0mm)/ Headless Compression Screw (5.2-7.0mm) are indicated for fixation of fractures of femur, tibia and calcaneus, and intra-articular fractures of knee joint.
8)The 3.5mm/4.0mm Headless Compression Screw, Oblique are indicated for fixation of bone fractures or for bone reconstruction of the foot and hand, including calcaneus, talar, navicular, metacarpals, metatarsals and phalanges.
9)The 6.5mm Cannulated Screw are intended for fixation of fractures, fusions, osteotomies, non-unions, and malunions of long bones and long bone fragments, pelvis, sacrum, and the bones of the foot. These screws are also indicated for femoral neck fractures, slipped capital femoral epiphysis, an adjunct to DHS (Dynamic Hip System) in basilar neck fractures, tibial plateau fractures, ankle arthrodesis, intercondylar femur fractures, SI joint disruptions and subtalar arthrodesis.
10)The 7.3mm Cannulated Screws are intended for fixation of fractures, fusions, osteotomies, non-unions, and malunions of long bones and long bone fragments, pelvis, sacrum and the bones of the foot. These screws are also indicated for slipped capital femoral epiphysis, ankle arthrodesis and subtalar arthrodesis.

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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K221090- 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	January 10th, 2023
2. Proposed Device	
Trade/proprietary name	Metal Cannulated Screw
Common or usual name	Metal Cannulated 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 Systems **Additional Predicate Devices:** K143229 Nexis® osteosynthesis compressive screws K161616 DePuy Synthes 4.0 mm/4.5 mm/6.5 mm/7.3 mm Cannulated Screws K182361 Arthrex Compression FT Screws K170382 Arthrex Compression Screws K162353 MICA™ Screw System
Reason for 510(k) submission	New device (Implant)

4. Device Description

Metal Cannulated 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, Metal Cannulated Screw is used alone, 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 Cannulated Screw are made of Ti-6Al-4V ELI following

ASTM F 136. Metal Cannulated Screw is provided as non-sterile. The implants are intended for single-use only, while the instruments are reusable.

5. Indication for Use

Metal Cannulated Screw is indicated for internal fixation of fracture, fusion and correction of limb bone and metaphysis, hand and foot:

1)The 2.3mm No Profile Cannulated Screw is indicated for the fixing and stabilizing the elective osteotomies of the mid foot bones and the metatarsal and phalanges of the foot only.

2)The 3.0mm No Profile Cannulated Screw is indicated for internal fixation of bone fractures of ulna, radius, fibula, and small bones (metacarpals, metatarsals, and phalanges).

3)The 4.0mm No Profile Cannulated Screw and 4.0mm No Profile Cannulated Screw, Oblique are indicated for fixation of fractures, fusions, osteotomies, non-unions, and malunions of small bones and small bone fragments.

4)The 5.0mm No Profile Cannulated Screw and 5.0mm No Profile Cannulated Screw, Oblique are indicated for fixation of fractures, fusions, osteotomies, non-unions, and malunions of long bones and long bone fragments, and the bones of the hand and foot.

5)The 7.0mm No Profile Cannulated Screw and 7.0mm No Profile Cannulated Screw, Oblique are indicated for fixation of fractures, fusions, osteotomies, non-unions, and malunions of long bones and long bone fragments, pelvis, sacrum, and the bones of the foot. These screws are also indicated for femoral neck fractures, slipped capital femoral epiphysis, an adjunct to DHS (Dynamic Hip System) in basilar neck fractures, tibial plateau fractures, ankle arthrodesis, intercondylar femur fractures, SI joint disruptions and subtalar arthrodesis.

6)The Headless Cannulated Screw (2.5-4.5mm) /Headless Compression Screw (2.5-4.5mm) are indicated for fixation of fractures in large bones of humerus, ulna, radius, tibia and fibula, and small bones of the foot. These screws are also indicated for intra-articular fractures of knee and ankle joint.

7)The Headless Cannulated Screw (5.0-7.0mm)/ Headless Compression Screw (5.2-7.0mm) are indicated for fixation of fractures of femur, tibia and calcaneus, and intra-articular fractures of knee joint.

8)The 3.5mm/4.0mm Headless Compression Screw, Oblique are indicated for fixation of bone fractures or for bone reconstruction of the foot and hand, including calcaneus, talar, navicular, metacarpals, metatarsals and phalanges.

9)The 6.5mm Cannulated Screw are intended for fixation of fractures, fusions, osteotomies, non-unions, and malunions of long bones and long bone fragments, pelvis, sacrum, and the bones of the foot. These screws are also indicated for femoral neck fractures, slipped capital femoral

epiphysis, an adjunct to DHS (Dynamic Hip System) in basilar neck fractures, tibial plateau fractures, ankle arthrodesis, intercondylar femur fractures, SI joint disruptions and subtalar arthrodesis.

10)The 7.3mm Cannulated Screws are intended for fixation of fractures, fusions, osteotomies, non-unions, and malunions of long bones and long bone fragments, pelvis, sacrum and the bones of the foot. These screws are also indicated for slipped capital femoral epiphysis, ankle arthrodesis and subtalar arthrodesis.

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 Cannulated 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 Cannulated 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 Cannulated 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.