August 24, 2018

Double Medical Technology Inc.
Yan Zuo
Regulatory Specialist
No. 18, Shanbianhong East Road, Haicang District
Xiamen, Fujian 361026
People's Republic of China

Re: K172830
Trade/Device Name: Double Medical Femoral Nail System
Regulation Number: 21 CFR 888.3020
Regulation Name: Intramedullary Fixation Rod
Regulatory Class: Class II
Product Code: HSB, HWC
Dated: June 28, 2018
Received: June 28, 2018

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Peter G. Allen -S
2018.08.24 14:52:30 -04'00'

FOR: Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K172830

Device Name
Double Medical Femoral Nail System

Indications for Use *(Describe)*
Double Medical Femoral Nail System is intended for femoral fracture fixation and promoting femoral fracture healing.

Indications for use of the Proximal Femoral Nail, Anti-rotation, short; and Anatomical Proximal Femoral Nail (APFN), short (Length 170 mm - 240 mm) include:
– Pertrochanteric fractures (31-A1 and 31-A2);
– Intertrochanteric fractures (31-A3);
– High subtrochanteric fractures (32-A1).

Indications for use of the Proximal Femoral Nail, Anti-rotation, long (Length 300 mm - 420 mm), Anatomical Proximal Femoral Nail (APFN), long (Length 300 mm - 480 mm) include:
– Low and extended subtrochanteric fractures;
– Ipsilateral trochanteric fractures;
– Combination fractures (in the proximal femur);
– Pathological fractures.

Indications for use of the Universal Femoral Nail, Cannulated (UFN I) include:
– Femoral shaft fractures.

Indications for use of the Universal Femoral Nail II, Cannulated (UFN II) include:
– Standard Locking UFN II: femoral shaft fractures;
– Reconstruction Locking UFN II : femoral shaft combined with femoral neck fractures, subtrochanteric 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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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

Section 3 510(k) Summary

3.1 Submitter

Double Medical Technology Inc.
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Contact Person: Yan Zuo
Date Prepared: Jun. 26th, 2018

3.2 Proposed Device

Trade /Proprietary Name: Double Medical Femoral Nail System
Common or Usual Name: Double Medical Femoral Nail System
Classification Name: Intramedullary fixation rod
Smooth or threaded metallic bone fixation fastener
Regulation Number: 21 CFR 888.3020, 888.3040
Regulatory Classification: Class II
Product Code: HSB, HWC

3.3 Predicate Device

K070761	Sanatmetal Intramedullary Nails and Pins
K043431	Stryker Gamma3® Nail System
K040336	Synthes (USA) Lateral Entry Femoral Nail System

3.4 Device Description

Double Medical Femoral Nail System consists of a series of nails, spiral blades, locking screws, end caps and related instrument. The implants are provided in a variety of lengths and anatomical designs to accommodate the medullary canal of femur. All of the implants in the Double Medical Femoral Nail System are made of made of Ti-6Al-4V

following ISO 5832-3 or Ti-6Al-4V ELI following ASTM F 136, which are widely used for surgical implants with well-known biocompatibility. Double Medical Femoral Nail System is provided as non-sterile.

3.5 Indication for Use

Double Medical Femoral Nail System is intended for femoral fracture fixation and promoting femoral fracture healing.

- Indications for use of the Proximal Femoral Nail, Anti-rotation, short; and Anatomical Proximal Femoral Nail (APFN), short (Length 170 mm - 240 mm) include:
  - Pertrochanteric fractures (31-A1 and 31-A2);
  - Intertrochanteric fractures (31-A3);
  - High subtrochanteric fractures (32-A1).
- Indications for use of the Proximal Femoral Nail, Anti-rotation, long (Length 300 mm - 420 mm), Anatomical Proximal Femoral Nail (APFN), long (Length 300 mm - 480 mm) include:
  - Low and extended subtrochanteric fractures;
  - Ipsilateral trochanteric fractures;
  - Combination fractures (in the proximal femur);
  - Pathological fractures.
- Indications for use of the Universal Femoral Nail, Cannulated (UFN I) include:
  - Femoral shaft fractures.
- Indications for use of the Universal Femoral Nail II, Cannulated (UFN II) include:
  - Standard Locking UFN II: femoral shaft fractures;
  - Reconstruction Locking UFN II : femoral shaft combined with femoral neck fractures, subtrochanteric fractures.

3.6 Comparison 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

3.7 Non-Clinical Performance Data

Non-Clinical tests were conducted to verify that the proposed device met all design specifications as was Substantially Equivalent (SE) to the predicate device.

The test results demonstrated that the proposed device conforms to ASTM F1264-16e1 *Standard Specification and Test Methods for Intramedullary Fixation Devices,* ASTM F543-17 *Standard Specification and Test Methods for Metallic Medical Bone Screws*, ASTM F384-17 *Standard Specifications and Test Methods for Metallic Angled Orthopedic Fracture Fixation Devices*, including:

- Static Four-point Bending Test of Nail
- Dynamic Four-point Bending Test of Nail
- Static Torsion Test of Nail
- Static Three-point Bending Test of Locking Screw
- Dynamic Three-point Bending Test of Locking Screw
- Insertion/removal Test of Locking Screw
- Pullout Test of Locking Screw
- Torsion Test of Locking Screw.
- Cantilever Bending Test
- Insertion/removal test, static torsion and axial pullout test of Lag Screw
- Cut-out Test

3.8 Clinical Performance Data

No clinical performance data is included in this submission.

3.9 Substantially Equivalent

The proposed device 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.