Section 3 510(k) Summary

MAY 2 1 2014

This 510(k) summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) Number: K131609

3.1 Date of Submission

May 31, 2013

3.2 Submission Correspondent

Mr. Da Zeng

Xiamen Double Engine Medical Material Co., Ltd.

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3.3 Proposed Device

Device Name: Double Engine Intramedullary Nail Systems

Classification: II

Product Code: HSB

Regulation Number: 21 CF 888.3020

Review Panel: Orthopedic

Material:

Double Engine Intramedullary Nail System is manufactured from titanium alloy that meets ASTM F1472.

Intended Use Statement:

Double Engine Intramedullary Nail System is intended to be implanted into the medullary canal of tibia for alignment, stabilization, fixation of fractures caused by trauma or disease.

3.4 Devices Description

Double Engine Intramedullary Nail System is composed of intramedullary nails, interlocking screws, and end caps. Intramedullary nails are provided in variety of lengths and anatomical deigns to accommodate the medullary canal of long bones (tibia). Interlocking screws are used for axial compression and preventing rotation. End caps on intramedullary nails are intended to facilitate removal and to allow length adjustment of the nail.

3.5 Predicate Device Information

K040762 Synthes (USA) Tibial Nail System EX

3.6 Non-Clinical Tests Conclusion

Bench tests were conducted to verify that the proposed device met all design specifications as was Substantially Equivalent (SE) to the predicate devices. The test results demonstrated that the proposed device complies with the ASTM F1264 (Standard Specification and Test Methods for Intramedullary Fixation Devices).

3.7 Substantially Equivalent Conclusion

As compared with predicate devices, equivalence for Double Engine Intramedullary Nail System is based on similarities of intended use, material, physical characteristics, geometric design, and mechanical strength. Therefore, Double Engine believes that there are sufficient evidences to conclude that the Double Engine Intramedullary Nail System is substantially equivalent to existing legally marketed devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

May 21, 2014

Xiamen Double Engine Medical Material Company, Limited
Mr. Da Zeng
218 Houxiang Road, Haicang District, Xiamen
3610022 Fujian
China

Re: K131609
Trade/Device Name: Double Engine Intramedullary Nail System
Regulation Number: 21 CFR 888.3020
Regulation Name: Intramedullary fixation rod
Regulatory Class: Class II
Product Code: HSB
Dated: April 18, 2014
Received: April 18, 2014

Dear Mr. Zeng:

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. 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); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Lori A. Wiggins

for
Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section 2 Statement of Intended Use

510(k) Number: K131609

Device Name: Double Engine Intramedullary Nail System

Intend Use Statement:

Double Engine Intramedullary Nail System is intended to be implanted into the medullary canal of tibia for alignment, stabilization, fixation of fractures caused by trauma or disease.

☒ PRESCRIPTION USE ☐ OVER-THE-COUNTER USE

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Casey L. Hanley, Ph.D.

Division of Orthopedic Devices