February 1, 2018

Double Medical Technology Inc.
Ms. Yan Zuo
Regulatory Specialist
No. 18 Shanbianhong East Road, Haicang District
Xiamen, 361026
CHINA

Re: K172828
Trade/Device Name: Double Medical Cage System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: MAX
Dated: January 10, 2018
Received: January 12, 2018

Dear Ms. 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. 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.

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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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,

Katherine D. Kavlock -S

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)*
K172828

Device Name
Double Medical Cage System

Indications for Use *(Describe)*
Double Medical Cage System is indicated for use in patients with degenerative disc disease (DDD) at one or two levels from L2 to L5 whose condition requires the use of interbody fusion combined with supplemental fixation. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. These patients should be skeletally mature and have had six months of non-operative treatment. The Cage should be packed with autogenous bone graft (i.e. autograft).

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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510(k) Summary

Submitter

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Contact Person: Yan Zuo Date
Prepared: Jan. 10th, 2018

Device

Trade /Proprietary Name: Double Medical Cage System
Common or Usual Name: Double Medical Cage System
Classification Name: Intervertebral Body Fusion Device
Regulation Number: 21 CFR 888.3080
Regulatory Classification: Class II
Product Code: MAX

Predicate Device

Primary predicate device:

K133053 Weigao Milestone Spinal System

Additional Predicates:

K100089 Synthes T-PAL Spacer

Device Description

Double Medical Cage System consists of cages of various lengths and heights, which can be inserted between two vertebral bodies to give support during interbody fusion surgeries. The cages consist of main bodies and marker pins. The main bodies are made of PEEK, which meets the requirements of ASTM F 2026-02 *Standard Specification for*

Polyetheretherketone (PEEK) Polymers for Surgical Implant Applications. Marker pins are made of Ti-6Al-4V following ASTM F 1472-14 *Standard Specification for Wrought Titanium-6Aluminum-4Vanadium Alloy for Surgical Implant Applications*.

Indication for Use

Double Medical Cage System is indicated for use in patients with degenerative disc disease (DDD) at one or two levels from L2 to L5 whose condition requires the use of interbody fusion combined with supplemental fixation. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. These patients should be skeletally mature and have had six months of non-operative treatment. The Cage should be packed with autogenous bone graft (i.e. autograft).

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

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 F2077 *Test Methods For Intervertebral Body Fusion Devices* and ASTM F2267 *Standard Test Method for Measuring Load Induced Subsidence of Intervertebral Body Fusion Device Under Static Axial Compression,* including:

- Static axial compression test
- Static compression shear test
- Dynamic axial compression test
- Dynamic compression shear test
- Subsidence Test

Clinical Performance Data

No clinical performance data is included in this submission.

Conclusion

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.