



Food and Drug Administration  
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August 22, 2016

Double Medical Technology Incorporated  
Mr. Da Zeng  
No. 18, Shanbianhong East Road, Haicang District  
Xiamen Fujian, 361026  
CHINA

Re: K151458

Trade/Device Name: Double Medical Universal Spine System  
Regulation Number: 21 CFR 888.3070  
Regulation Name: Pedicle screw spinal system  
Regulatory Class: Class II  
Product Code: MNI, MNH  
Dated: July 16, 2016  
Received: July 20, 2016

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 Parts 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" (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.

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,

Vincent J. Devlin -S

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

Enclosure

## Indications for Use

510(k) Number (if known)

K151458

Device Name

Double Medical Universal Spine System

Indications for Use (Describe)

Double Medical Universal Spine System is intended for posterior, non-cervical, pedicle fixation for the following indications: severe spondylolisthesis (grade 3 or 4) of the L5-S1 vertebrae; trauma (i.e. fracture or dislocation), spinal stenosis, curvatures (i.e. scoliosis, kyphosis, and/or lordosis), tumor, pseudarthrosis, and failed previous fusion. The device is to be used in skeletally mature patients, and for stabilization and immobilization of the spine as an adjunct to fusion with bone graft. The levels of fixation are T8 – S1.

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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## Section 3 510(k) Summary

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: K151458

### 3.1 Date of Submission

July 16th, 2016

### 3.2 Submission Correspondent

Mr. Da Zeng

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### 3.3 Proposed Device

**Trade /Proprietary Name:** Double Medical Universal Spine System

**Common Name:** Pedicle screw spinal system

**Classification Name:** Pedicle screw spinal system

**Device Classification:** II

**Classification Panel:** Orthopedic Panel

**Product Code:** MNI, MNH

**Regulation Number:** 21 CFR Part 888.3070

### 3.4 Predicate Devices Information

K082617 Trauson General Spinal System (GSS)

### **3.5 Device Description**

Double Medical Universal Spine System consists of pedicle screws, rods, transconnector and nut etc. It is made of Ti-6Al-4V ELI, which meets ASTM F 136 “Standard Specification for Wrought Titanium-6Aluminum-4Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications” and is widely used for surgical implants.

The proposed devices are provided non-sterile but sterilized by the end user.

### **3.6 Indication for Use/Intended Use**

Double Medical Universal Spine System is intended for posterior, non-cervical, pedicle fixation for the following indications: severe spondylolisthesis (grade 3 or 4) of the L5-S1 vertebrae; trauma (i.e. fracture or dislocation), spinal stenosis, curvatures (i.e. scoliosis, kyphosis, and/or lordosis), tumor, pseudarthrosis, and failed previous fusion. The device is to be used in skeletally mature patients, and for stabilization and immobilization of the spine as an adjunct to fusion with bone graft. The levels of fixation are T8 – S1.

### **3.7 Technological Characteristics**

Double Medical Universal Spine System components incorporate the same technological characteristics as the predicate device to stable the non-cervical posterior spine as an adjunct to fusion. At a high level, the subject and predicate device are based on the following same or equivalent technological elements:

- FDA Product Codes: MNI and MNH
- Equivalent intended uses
- Components are manufactured from Ti-6Al-4V ELI as per ASTM F 136
- Polyaxial and monoaxial pedicle screws are used to attach to the vertebrae
- Same pedicle screw thread form configuration
- Construct support mechanism
- Use of instrumentation to aid the placement of pedicle screws and rods
- Mechanical performance

### **3.8 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 device. The following tests were performed per ASTM F 1717-14 “Standard Test Methods for Spinal Implant Constructs in a

Vertebrectomy Model”:

- Static compression bending test
- Dynamic compression bending test
- Static torsion test.

And ASTM F 1798-13 “Standard Test Method for Evaluating the Static and Fatigue Properties of Interconnection Mechanisms and Subassemblies Used in Spinal Arthrodesis Implants”:

- Axial gripping capacity test

### **3.9 Substantially Equivalent Conclusion**

The information submitted in this premarket notification has compared Double Medical Universal Spine System to the predicate device in regard to intended use, material, function, sizes and mechanical test results. These comparisons demonstrate sufficient evidence to conclude that Double Medical Universal Spine System is Substantially Equivalent to the predicate devices.