NOV 22 2011

Attachment III 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: _____

1. Date of Submission: April 7, 2011

2. Sponsor
   Changzhou Orthmed Medical Instrument Co., Ltd
   No.177, Qinling Road, New Zone,
   Changzhou, Jiangsu, China, 213022

   Establishment Registration Number: 3005596372

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   Position: Quality Manager
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3. Submission Correspondent
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   Mid-Link Consulting Co., Ltd
   P.O. Box 237-023, Shanghai, 200237, China
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4. Proposed Device Identification

   Proposed Device Name: Devine Spinal System
   Proposed Device Model: TL5.5, TL6.0, TL6.35
   Classification: II
   Product Code: MNH, MNI
   Regulation Number: 21 CFR 888.3070
   Review Panel: Orthopedic
   Intended Use Statement:

Devine Spinal System is intended for posterior pedicle screw fixation of the non-cervical posterior spine in skeletally mature patients. It provides stabilization and immobilization of spinal segments as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities: (1) trauma (i.e. fracture or dislocation), (2) curvatures (scoliosis, kyphosis, and/or lordosis), (3) spinal tumor, (4) failed previous fusion (5) pseudarthrosis, (6) spinal stenosis. It is not intended for pedicle screw fixation above T8.

5. Predicate Device Identification

510(k) Number: K082617
Product Name: Trauson General Spinal System (GSS)
Manufacturer: TRAUSON (JIANGSU) MEDICAL INSTRUMENT CO., LTD.

6. Device Description

The proposed devices of Devine Spinal System is intended for posterior pedicle screw fixation of the non-cervical posterior spine in skeletally mature patients. It provides stabilization and immobilization of spinal segments as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities: (1) trauma (i.e. fracture or dislocation), (2) curvatures (scoliosis, kyphosis, and/or lordosis), (3) spinal tumor, (4) failed previous fusion (5) pseudarthrosis, (6) spinal stenosis.

It is made of Titanium Alloy (Ti-6AL-4V), which meet ASTM F136-02a, Standard Specification for Wrought Titanium-6 Aluminum-4 Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications, which are widely used for surgical implants with well known biocompatibility.

The proposed device includes three models, which are TL5.5, TL6.0 and TL6.35. All models use the same material, and same design principle. The only difference is the parts size which does not affect the design. There is no surface modified or coated.

The proposed device consists of the following components: FAS, Reduction FAS, Spine Hook, Rod and Crosslink Plate

The proposed devices are not provided sterile. It is required to be sterilized via autoclave method to reach a SAL of 10^{-6} by the hospital prior to surgery. The sterilization method is presented in the user manual, which was validated per ISO 17665-1: 2006 Sterilization of health care products – Moist heat – Part 1: Requirements for the development, validation, and routine control of a sterilization process for medical devices.

7. Non-Clinical Test 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 test results demonstrated that the proposed

device complies with the following standards:

ASTM F1717-09 , Standard Test Methods for Spinal Implant Constructs in a Vertebrectomy Model

The specific tests performed according to ASTM F1717 to evaluate the mechanical performance of the proposed device includes: static axial compression, dynamic axial compression, and static torsion.

8. Substantially Equivalent Conclusion

The proposed device, Devine Spinal System, is determined to be Substantially Equivalent (SE) to the predicate device, Trauson General Spinal System (GSS) (K082617), in respect of safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

NOV. 22 2011

Changzhou Orthmed Medical Instrument Co., Ltd.
% Mid-Link Consulting Co., Ltd.
Ms. Diana Hong
P. O. Box 237-023
Shanghai, 200237, China

Re: K111690
Trade/Device Name: Devine Spinal System
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle screw spinal system
Regulatory Class: Class II
Product Code: MNH, MNI
Dated: November 21, 2011
Received: November 21, 2011

Dear Ms. Hong:

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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 Small Manufacturers, International and Consumer Assistance 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,

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

Enclosure

Attachment II Indications for Use

510(k) Number: K111690
Device Name: Devine Spinal System

Indications for Use:

Devine Spinal System is intended for posterior pedicle screw fixation of the non-cervical posterior spine in skeletally mature patients. It provides stabilization and immobilization of spinal segments as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities: (1) trauma (i.e. fracture or dislocation), (2) curvatures (scoliosis, kyphosis, and/or lordosis), (3) spinal tumor, (4) failed previous fusion (5) pseudarthrosis, (6) spinal stenosis. It is not intended for pedicle screw fixation above T8.

☒PRESCRIPTION USE
(Part 21 CFR 801 Subpart D)

☐OVER-THE-COUNTER USE
(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)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K111690