October 10, 2018

Jiangsu Trauhui Medical Instrument Co.,Ltd.
% Mike Gu
Regulatory Affairs Manager
Guangzhou Osmunda Medical Device Technical Service Co.,Ltd.
8-9Th Floor, R&D Building, No.26 Qinglan Street
Panyu District
Guangzhou, 510006 CN

Re: K172826
Trade/Device Name: Cellent Spinal Systems
Regulation Number: 21 CFR 888.3070
Regulation Name: Thoracolumbosacral Pedicle Screw Systems
Regulatory Class: Class II
Product Code: NKB
Dated: August 28, 2018
Received: August 27, 2018

Dear Mike Gu:

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,

Colin O'neill -S
for MNM

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K172826

Device Name
Cellent Spinal Systems

Indications for Use *(Describe)*
Cellent Spinal Systems are 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.
Cellent Spinal Systems are not intended for pedicle screw fixation above T8.

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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TRAUHUI

510(k) Summary

In accordance with 21 CFR 807.92 the following summary of information is provided:

1. SUBMITTER

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Date prepared	Sep 20, 2018

2. DEVICE

Device Name:	Cellent Spinal Systems
Common/Usual Name:	Cellent Spinal Systems
Regulation number	21 CFR 888.3070
Regulation Name	Thoracolumbosacral Pedicle Screw System
Regulation Class:	II
Product Code:	NKB

3. PREDICATE DEVICES

Primary predicate device: K161151, Spinal fixation system

Additional predicate device: K082617, Trauson General Spinal System (GSS)

4. DEVICE DESCRIPTION

Cellent Spinal System is a combination of pedicle screws, pedicle hooks, rods, set screws, connectors, and cross links, which can fix the vertebral body through pedicle or lamina.

It is made of Titanium Alloy (Ti-6AL-41V ELI), which meet ASTM F136-13, 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.

5. INDICATIONS FOR USE

Cellent Spinal Systems are 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.
Cellent Spinal Systems are not intended for pedicle screw fixation above T8.

6. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

Cellent Spinal System is substantially equivalent to the cleared primary predicate device, the Spinal fixation system (K161151) because it has same indications for use, is composed of the same materials, and has similar technological characteristics. Differences between the subject and predicate devices include sizes of pedicles and screws. The differences in technological characteristics do not raise different questions of safety and effectiveness. In addition, Cellent Spinal System meets or exceeds the performance of the predicate devices in ASTM F1717 and ASTM F1798 bench tests.

7. NON-CLINICAL DATA

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The following non-clinical data were provided in support of the substantial equivalence determination.

Performance testing

Comparative performance tests (static and dynamic compression bending and static torsion) were conducted between Cellent Spinal System and the predicate device, according to ASTM F1717-15 Standard Test Methods for Spinal Implant Constructs in a Vertebrectomy Model, and static axial and torsional gripping capacity testing per ASTM F1798-13 Standard Guide For Evaluating The Static And Fatigue Properties Of Interconnection Mechanisms And Subassemblies Used In Spinal Arthrodesis Implants. The performance differences between proposed device and predicate device will not affect the safety and effectiveness of the proposed device. It demonstrates substantial equivalences to the predicate device.

Animal Study

The subject of this premarket submission, Cellent Spinal System, does not require animal studies to support substantial equivalence.

8. CLINICAL DATA

The subject of this premarket submission, Cellent Spinal System, did not require clinical studies to support substantial equivalence.

9. CONCLUSION

The differences between the Cellent Spinal System and its predicate devices do not raise different questions of safety and effectiveness. The non-clinical data support substantial equivalence of the device and the performance testing report demonstrate that the Cellent Spinal System should perform as intended in the specified use conditions.

From the results of non-clinical data including the performance testing and comparative performance testing described, Jiangsu Trauhui Medical Instrument Co., Ltd. concludes that the Cellent Spinal System is substantially equivalent to the predicate devices.