January 15, 2019

Evolution Spine, LLC
Mr. Douglas Davis
Vice President of Product Development
4225 Office Parkway
Dallas, Texas 75204

Re: K182478
Trade/Device Name: Whistler Modular Pedicle Screw System
Regulation Number: 21 CFR 888.3070
Regulation Name: Thoracolumbosacral pedicle screw system
Regulatory Class: Class II
Product Code: NKB
Dated: December 6, 2018
Received: December 10, 2018

Dear Mr. Davis:

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,

Ronald P. Jean -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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K182478

Device Name
Whistler Modular Pedicle Screw System

Indications for Use *(Describe)*
The Whistler Modular Pedicle Screw System is intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of thoracic, lumbar, and sacral spine: degenerative disc disease (DDD) (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies); spondylolisthesis; trauma (i.e., fracture or dislocation); spinal stenosis; curvatures (i.e., scoliosis, kyphosis, and/or lordosis); tumor; pseudoarthrosis; and failed previous fusion.

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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1. 510(k) Summary

I. SUBMITTER

Evolution Spine, LLC

4225 Office Parkway

Dallas, TX 75204

Contact person: Douglas Davis

Phone: (214) 228-6252

Date prepared: September 5, 2018

II. DEVICE

Name of the device: Whistler Modular Pedicle Screw System

Common or usual name: Pedicle Screw System

Classification name: Thoracolumbosacral Pedicle Screw System

Regulatory Class: 2

Regulation Number: 21 CFR 888.3070

Product Code: NKB

III. PREDICATE DEVICES

CREO Stabilization System (K180210)- primary predicate

Modera Modular Pedicle Screw System (K141253)- reference predicate

U&I Corporation OPTIMA Pedicle Screw System (K031585) – reference predicate

Biomet Synergy VLS Open (K973836) – reference predicate

DePuy Moss Miami Spinal System (K962628) – reference predicate

IV. DEVICE DESCRIPTION

The Whistler Modular Pedicle Screw System is a multiple component, posterior spinal fixation system which consists of pedicle screws, rods, and locking cap set screws. All of the components are available in a variety of sizes to match more closely to the patient's anatomy. All implant components are made from titanium alloy (ASTM F136).

The Whistler Modular Pedicle Screw System is provided in both non-sterile and sterile forms. All implants are intended for single use only.

V. INDICATIONS FOR USE

The Whistler Modular Pedicle Screw System is intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of thoracic, lumbar, and sacral spine: degenerative disc disease (DDD) (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies); spondylolisthesis; trauma (i.e., fracture or dislocation); spinal stenosis; curvatures (i.e., scoliosis, kyphosis, and/or lordosis); tumor; pseudoarthrosis; and failed previous fusion..

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The subject and predicate devices are based on the following same technological elements:

- all devices are utilized in posterior surgical approaches
- all devices are fabricated from Titanium alloy meeting the specifications of ASTM F136, where HA coated all devices meet the specifications of ASTM 1185
- Devices are supplied in both sterile and non-sterile forms, intended for single use only

The subject Whistler Modular Pedicle Screw System has the same technological characteristics as the predicate devices including design, intended use, material composition, function and range of sizes. Specific examples of shared characteristics include the following:

- Devices intended for non-cervical pedicle screw fixation
- 5.5mm and 6.0mm diameter rods
- Screws diameters ranging from a nominal 4.75mm to 10.5mm
- Screw lengths ranging from 25mm to 120mm
- Screws with cannulated and solid options
- Tulips with Open, Reduction, and MIS options
- Screws offered with and without hydroxyapatite coating

VII. PERFORMANCE DATA

The following performance data were provided in support of the substantial equivalence.

- Static Axial Compression Bending (ASTM F1717)
- Static Torsion (ASTM F1717)
- Dynamic Axial Compression Bending (ASTM F1717)

- Static A-P load (ASTM F1798)

VIII. CONCLUSIONS

The design testing performed for the Whistler Modular Pedicle Screw System demonstrated that the performance of the device is substantially equivalent to the legally marketed predicate devices.