December 18, 2019

joimax GmbH
Mr. Gary Mocnik
Offical Correspondent
Amalienbadstrasse 41
RaumFabrik 61
76227 Karlsruhe
GERMANY

Re: K192680
Trade/Device Name: Percusys® Plus Pedicle Screw System
Regulation Number: 21 CFR 888.3070
Regulation Name: Thoracolumbosacral pedicle screw system
Regulatory Class: Class II
Product Code: NKB
Dated: July 26, 2019
Received: September 26, 2019

Dear Mr. Mocnik:

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/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-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, Ph.D.
Director (Acting)
DHT6B: Division of Spinal Devices
OHT6: Office of Orthopedic Devices
Office of Product Evaluation and Quality
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)*
K192680

Device Name
Percusys® Plus Pedicle Screw System

Indications for Use *(Describe)*
The Percusys® Plus 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.

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510(k) Summary

I. SUBMITTER

joimax® GmbH
Amalienbadstrasse 41
RaumFabrik 61
76227 Karlsruhe- Germany

Contact person: Gary Mocnik
Phone: (949) 433-0413
Date prepared: December 8, 2019

II. DEVICE

Name of the device: Percusys® Plus 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 DEVICE

MIS Z-Pedicle Screw System (K143200)- primary predicate
This predicate has not been subject to a design-related recall
CREO Stabilization System (K180210)- reference predicate This predicate has not been subject to a design-related recall

IV. DEVICE DESCRIPTION

The Percusys® Plus Pedicle Screw System is a multiple component, posterior spinal fixation system which consists of pedicle screws and rods. 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 Percusys® Plus Pedicle Screw System is provided in sterile form. All implants are intended for single use only.

V. INDICATIONS FOR USE

The Percusys® Plus 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

At a high level, 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
- Devices are supplied in sterile form, intended for single use only

The subject Percusys® Plus Pedicle Screw System has the same technological characteristics as the predicate device including design, intended use, material composition, function and range of sizes.

VII. PERFORMANCE DATA

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

- Dynamic Axial Compression Bending (ASTM F1717)
- Dynamic Flexion Bending (ASTM F1798)
- Buckling Test
- Torsion Testing
-

The Percusys® Plus Pedicle Screw System met all specified criteria and did not raise new safety or performance questions. Based on the performance testing the Percusys® Plus Pedicle Screw System was found to have a safety and effectiveness profile that is similar to the predicate device.

VIII. CONCLUSIONS

The design testing performed for the Percusys® Plus Pedicle Screw System demonstrated that the performance of the device is equal to the legally marketed predicate devices.