February 13, 2020

OrthoCircle Spine
℅ Nathan Wright
Engineer & Regulatory Specialist
Empirical Testing Corp.
4628 Northpark Drive
Colorado Springs, Colorado 80918

Re: K193472
Trade/Device Name: OrthoCircle Spine Pedicle Screw System
Regulation Number: 21 CFR 888.3070
Regulation Name: Thoracolumbosacral Pedicle Screw System
Regulatory Class: Class II
Product Code: NKB, KWQ
Dated: December 13, 2019
Received: December 16, 2019

Dear Nathan Wright:

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,

for

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 on last page.

510(k) Number *(if known)*
K193472

Device Name
OrthoCircle Spine Pedicle Screw System

Indications for Use *(Describe)*

The OrthoCircle Spine Pedicle Screw System is a thoracolumbosacral (T1-S1) spinal fixation system containing devices intended for use as a posterior pedicle screw fixation system. Pedicle screw fixation is limited to skeletally mature patients. These devices are indicated as an adjunct to fusion for all the following indications: degenerative disc disease (defined as discogenic back pain 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, and/or failed previous fusion (pseudoarthrosis).

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.

5. 510(K) SUMMARY

Submitter's Name:	OrthoCircle Spine
Submitter's Address:	15 East Montgomery Crossroads, Suite 3 Savannah, GA 31406
Submitter's Telephone:	888-463-5803
Contact Person:	Nathan Wright MS Empirical Testing Corp. 719-351-0248 nwright@empiricaltech.com
Date Summary was Prepared:	13-Dec-2019
Trade or Proprietary Name:	OrthoCircle Spine Pedicle Screw System
Common or Usual Name:	thoracolumbosacral pedicle screw system
Classification:	Class II per 21 CFR §888.3070
Product Code:	NKB, KWQ
Classification Panel:	Division of Orthopedic Devices

DESCRIPTION OF THE DEVICE SUBJECT TO PREMARKET NOTIFICATION:

The OrthoCircle Spine Pedicle Screw System is a titanium alloy implant device to be implanted from the posterior approach. The system consists of rods, poly-axial screws and set screws. The screws are available in diameters from Ø4.50mm to Ø7.50mm and in lengths of 20mm to 60mm. Standard and Reduction Pedicle Screws are available in these sizes. Titanium rods are available in Ø5.50mm diameter straight and pre-contoured. Set screws are used to fasten the rods and poly-axial screws. Implants are provided sterile in individual packaging.

Special instruments are used to implant the pedicle system. Instruments used to implant the pedicle screw system are provided as non-sterile and require sterilization prior to use.

INDICATIONS FOR USE

The OrthoCircle Spine Pedicle Screw System is a thoracolumbosacral (T1-S1) spinal fixation system containing devices intended for use as a posterior pedicle screw fixation system. Pedicle screw fixation is limited to skeletally mature patients. These devices are indicated as an adjunct to fusion for all the following indications: degenerative disc disease (defined as discogenic back pain 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, and/or failed previous fusion (pseudoarthrosis).

TECHNOLOGICAL CHARACTERISTICS

The OrthoCircle Spine Pedicle Screw System implants are made from Ti-6Al-4V ELI conforming to ASTM F1472. The subject and predicate devices have nearly identical technological characteristics and the minor difference do not raise any new issues of safety and

effectiveness. Specifically, the following characteristics are similar between the subject and predicates:

- Indications for Use
- Materials of manufacture
- Structural support mechanism
- Sizes

Table 5-1 Predicate Devices

510k Number	**Trade or Proprietary or Model Name**	**Manufacturer**	**Predicate Type**
K171170	M.U.S.T. Pedicle Screw System	Medacta International SA	Primary
K191576	Mercury® Spinal System	Spinal Elements, Inc.	Additional

PERFORMANCE DATA

The OrthoCircle Spine Pedicle Screw System has been tested in the following test modes:

- Static compression bending per ASTM F1717-18
- Static torsion per ASTM F1717-18
- Dynamic compression bending per ASTM F1717-18

The results of this non-clinical testing show that the strength of the OrthoCircle Spine Pedicle Screw System is sufficient for its intended use and is substantially equivalent to legally marketed predicate devices.

CONCLUSION

The overall technology characteristics and mechanical performance data lead to the conclusion that the OrthoCircle Spine Pedicle Screw System is substantially equivalent to the predicate device.