Ortho Development Corporation
Darlene Hull
Director of Regulatory & Clinical Affairs
12187 South Business Park Drive
Draper, Utah 84020

July 14, 2021

Re: K203023
Trade/Device Name: Pisces Spinal System
Regulation Number: 21 CFR 888.3070
Regulation Name: Thoracolumbosacral Pedicle Screw System
Regulatory Class: Class II
Product Code: NKB
Dated: June 4, 2021
Received: June 7, 2021

Dear Darlene Hull:

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

Colin O'Neill, M.B.E.
Assistant Director
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)*
K203023

Device Name
Pisces Spinal System

Indications for Use *(Describe)*
The Pisces Spinal System is intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion using autograft or allograft. This system is intended for posterior, non-cervical pedicle fixation of the thoracic, lumbar, sacrum and iliac spine (T1-Sacrum/Ilium) for the following indications:
1. Degenerative disc disease (DDD) (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies)
2. Degenerative Spondylolisthesis with objective evidence of neurologic impairment
3. Trauma (fracture or dislocation)
4. Spinal tumor
5. Failed previous fusion (pseudarthrosis)
6. Spinal stenosis
7. Spinal deformities or curvatures such as scoliosis, kyphosis, or lordosis

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

In accordance with Title 21 of the Code of Federal Regulations, Part 807, and in particular 21 CFR §807.92, the following summary of information is provided:

Name of the Sponsor	Ortho Development® Corporation 12187 South Business Park Drive Draper, Utah 84020
510(k) Primary Contact	Darlene Hull Director of Regulatory & Clinical Affairs Telephone: (801) 619-3499 Email: dhull@orthodevelopment.com
Date Prepared:	September 30, 2020
Submission Type:	Traditional 510(k)
Proprietary Name:	Pisces Spinal System
Common Name:	Thoracolumbosacral Pedicle Screw System
Classification:	21 CFR 888.3070
Device Class:	Class II
Product Code:	NKB
Primary Predicate:	Pagoda Pedicle Screw System (K131785)
Secondary Predicate:	Ibis Pedicle Screw System (K142146)

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Device Description:

The Pisces Spinal System is an implantable system intended to provide immobilization and stabilization of spine segments. The subject device is a modular pedicle screw assembly that consists of pedicle screws with solid and cannulated options, modular tulips in standard, reduction, and extended tab configurations, spinal rods, and set screws. All components are made of implantable-grade titanium.

The modular tulip is an assembly which consists of a tulip body, a saddle, and a locking ring. The top of the tulip body receives a locking set screw which secures the tulip body assembly to an ø5.5mm or ø6.0mm rod and pedicle screw when tightened.

The pedicle screw has a spherical head which the tulip assembly snaps onto either before or after surgical insertion. The 5.5mm or 6.0mm rod is inserted into the tulip assembly. After assembly of multiple pedicle screws, a set screw is inserted into the tulip and locked to a predetermined locking torque, immobilizing the construct. For the 20mm reduction and 90mm extended tab tulips, the guide tabs are removed from the construct following final lock. 20mm reduction tabs can be used to provide length for rod reduction while 90mm tab tulips facilitate minimally invasive surgeries (MIS). All implants are provided sterile for single use only.

Indication for Use:

The Pisces Spinal System is intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion using autograft or allograft. This system is intended for posterior, non-cervical pedicle fixation of the thoracic, lumbar, sacrum and iliac spine (T1-Sacrum/Ilium) for the following indications:

1. Degenerative disc disease (DDD) (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies)
2. Degenerative Spondylolisthesis with objective evidence of neurologic impairment
3. Trauma (fracture or dislocation)
4. Spinal tumor
5. Failed previous fusion (pseudarthrosis)

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6. Spinal stenosis
7. Spinal deformities or curvatures such as scoliosis, kyphosis, or lordosis

Comparison of Technological Characteristics:

The Pisces Spinal System is technologically similar to the already cleared predicate device Pagoda Pedicle Screw System and Ibis Pedicle Screw System in terms of Indication for use/intended use, material, technological characteristics, mechanical performance, and principle of operation.

Performance Data

Sterilization

Pisces Spinal System is gamma radiation sterilized and was validated to a sterility assurance level of 10^{-6} in accordance with the following standards:

- ISO 11137-1: 2006, Am1: 2013, Sterilization of health care products – Requirements for validation and routine control – Radiation sterilization; and
- ISO 11137-2:2013, Sterilization of health care products – Radiation – Part 2: Establishing the sterilization dose

Validation results indicate that the Pisces Spinal System complies with the standards.

Shelf Life

The packaging for Pisces Spinal System was validated in accordance with the following standards:

- ISO 11607-1: 2006 Packaging for terminally sterilized medical devices – Part 1: requirements for materials, sterile barrier systems and packaging systems; and
- ISO 11607-2: 2006 Packaging for terminally sterilized medical devices – Part 2: Validation requirements for forming, sealing and assembly processes.

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Validation results indicate that the packaging for the Pisces Spinal System complies with the standards.

Biocompatibility

The Pisces Spinal System contact materials were verified in accordance with the following standards:

- ISO 10993-1: 2009, Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process.
- ANSI/AAMI ST72:2011

Validation results indicated that the patient contact materials comply with the standard.

Mechanical Testing

The following mechanical testing were performed on the Pisces Spinal System

- Static Compression Testing per ASTM F1717
- Dynamic Compression Testing per ASTM F1717
- Static Torsion Testing per ASTM F1717
- Flexion-Extension Testing per ASTM F1798
- Static Anterior-Posterior Loading Testing per ASTM F1798

Bacterial Endotoxin Testing

Bacterial endotoxin testing is performed per ANSI/AAMI ST72:2011 using the limulus amebocyte lysate (LAL) pyrogen testing methodology at a test limit of 20 EU/device. Testing met the predetermined acceptance criteria. Routine monitoring of endotoxins in the manufacturing process is performed quarterly.

Clinical Testing

None provided for basis of substantial equivalence

Substantial Equivalence Conclusion:

Verification and Validation activities were conducted to establish the performance of the Pisces Spinal System. The results of these activities demonstrate that the Pisces Spinal System is as safe, as effective, and performs as well as or better than legally marketed predicates.

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Based on similarities in indications for use/intended use, material, technological characteristics, mechanical performance, and principle of operation, the Pisces Spinal System is considered substantially equivalent to the previously cleared predicate devices.