March 31, 2020

Ortho Development® Corporation
Ms. Divya Palan
Regulatory Affairs Specialist
12187 South Business Park Drive
Draper, Utah 84020

Re: K200281
Trade/Device Name: The Gecko Spinal System
Regulation Number: 21 CFR 888.3010
Regulation Name: Bone Fixation Cerclage
Regulatory Class: Class II
Product Code: OWI
Dated: January 31, 2020
Received: February 4, 2020

Dear Ms. Palan:

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,

Colin O'neill -S for

Colin O'Neill, M.B.E.
Acting 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)*

K200281

Device Name
The Gecko Spinal System

Indications for Use *(Describe)*

The Gecko Spinal System is a temporary implant for use in orthopedic surgery. The system is intended to provide temporary stabilization as a bone anchor during the development of solid bony fusion and aid in the repair of bone fractures. The indications for use include the following applications:

1. Spinal trauma surgery, used in sublaminar or facet wiring techniques;
2. Spinal reconstructive surgery, incorporated into constructs for the purpose of correction of spinal deformities such as idiopathic and neuromuscular scoliosis in patients 8 years of age and older, adult scoliosis, kyphosis and spondylolisthesis;
3. Spinal degenerative surgery, as an adjunct to spinal fusions.

The Gecko Spinal System may also be used in conjunction with other Ortho Development's spinal rod systems made of similar metals whenever "wiring" may help secure the attachment of the other implants.

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:	Divya S. Palan Regulatory Affairs Specialist Telephone: (801) 619-8922 Email: dpalan@orthodevelopment.com
510(k) Secondary Contact:	Darlene Hull Senior Regulatory Affairs Manager Telephone: (801) 619-3499 Email: DHull@orthodevelopment.com
Date Prepared:	January 31st 2020
Submission Type:	Traditional 510(k)
Proprietary Name:	The Gecko Spinal System
Common Name:	Spinal Fixation System
Classification:	21 CFR § 888.3010 – Bone Fixation Cerclage
Device Class:	Class II
Device Product Code:	OWI
Primary Predicate Device:	NAJA™ Ligament Correction System (K172206) Cousin Biotech S.A.S
Secondary Predicate Device:	Universal Clamp Spinal Fixation System (K142053) Zimmer Spine, Inc.

Device Description:

The Gecko Spinal System is an implantable device intended to provide immobilization and stabilization of spinal segments. The device consists of an implantable polyethylene terephthalate (PET) braided band with a stiffened guiding section at one end and a metal leader at the other (both removed before final implantation), an implantable grade titanium alloy clamp that mates with 5.5mm diameter rods, and an implantable grade titanium alloy nut that secures the band, clamp, and connecting rod together.
All implants are provided sterile for single use only; the implant should not be re-used or re-sterilized under any circumstances.

Indication for Use:

The Gecko Spinal System is a temporary implant for use in orthopedic surgery. The system is intended to provide temporary stabilization as a bone anchor during the development of solid bony fusion and aid in the repair of bone fractures. The indications for use include the following applications:

1. Spinal trauma surgery, used in sublaminar or facet wiring techniques;
2. Spinal reconstructive surgery, incorporated into constructs for the purpose of correction of spinal deformities such as idiopathic and neuromuscular scoliosis in patients 8 years of age and older, adult scoliosis, kyphosis and spondylolisthesis;
3. Spinal degenerative surgery, as an adjunct to spinal fusions.

The Gecko Spinal System may also be used in conjunction with other Ortho Development's spinal rod systems made of similar metals whenever "wiring" may help secure the attachment of the other implants.

Comparison of Technological Characteristics:

The Gecko Spinal System is technologically similar to the already cleared predicate device NAJA™ Ligament Correction System and, Universal Clamp Spinal Fixation System in terms of intended use/indication for use, technological characteristics, device materials, mechanical performance, and function.

Performance Data

Sterilization

The Gecko 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 indicates that the Gecko Spinal System complies with the standards.

Shelf Life

The packaging for the Gecko 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

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

Biocompatibility

The Gecko Spinal System patient 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.

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

Mechanical Testing

The following mechanical testing were performed on the Gecko Spinal System:

- Static and dynamic band tension testing per ASTM F1798
- Static axial grip and static torsional grip testing per ASTM F1798
- Static and Dynamic axial compression testing per ASTM F1717

Test results demonstrates that the Gecko Spinal System has substantially equivalent mechanical performance as the identified predicate devices.

Clinical Testing

None provided for basis of substantial equivalence

Substantial Equivalence Conclusion:

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

Based on similarities in intended use/indication for use, technological characteristics, device materials, mechanical performance and function the Gecko Spinal System is considered substantially equivalent to the previously cleared predicate devices.