August 21, 2023

OrthoPediatrics Corp.
Yan Li
Regulatory Affairs Manager
2850 Frontier Drive
Warsaw, Indiana 46582

Re: K231266
Trade/Device Name: Pediatric Nailing Platform | Tibia
Regulation Number: 21 CFR 888.3020
Regulation Name: Intramedullary fixation rod
Regulatory Class: Class II
Product Code: HSB
Dated: July 21, 2023
Received: July 21, 2023

Dear Yan Li:

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,

Farzana Sharmin -S
Digitally signed by Farzana Sharmin -S
Date: 2023.08.21 16:57:46 -04'00'

Farzana Sharmin, Ph.D.
Assistant Director
DHT6A: Division of Joint Arthroplasty 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)*
K231266

Device Name
Pediatric Nailing Platform | Tibia

Indications for Use *(Describe)*
The Pediatric Nailing Platform | Tibia is intended as a temporary implant for alignment, stabilization and fixation of tibias that have been surgically prepared (osteotomy) for correction of deformities or have sustained fracture due to trauma or disease. The patient population is pediatric, including child and adolescent subgroups, and small-stature adults - such as patient with small intramedullary canals affected by skeletal dysplasias, osteogenesis imperfecta or other bone diseases. Nail lengths greater than 400mm are for skeletally mature patients.

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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510(k) Summary

I. Submitter

Submission:	Traditional 510(k) Premarket Notification
Applicant:	OrthoPediatrics Corp.
Applicant Address:	2850 Frontier Drive, Warsaw, IN 46582
Establishment Registration Number:	3006460162
Contact:	Yan Li
Contact Phone:	(574) 267-0864
Date Prepared:	August 18, 2023

II. Device

Device Trade Name:	Pediatric Nailing Platform | Tibia
Regulation Number:	21 CFR 888.3020
Regulation Name:	Intramedullary Fixation Rod
Device Classification:	II
Classification Panel:	Orthopedic
Classification Product Code:	HSB
Device Classification Name	Rod, Fixation, Intramedullary and Accessories

III. Predicate Device and Reference Device

Substantial equivalence is claimed to the following predicate device:

Predicate Device:

- Primary predicate: Simple Locking Intramedullary (SLIM) System
  (K192710, Pega Medical Inc., now owned by OrthoPediatrics Corp.)
- Secondary predicate: GAP Endo-Exo Medullary System
  (K160545, Pega Medical Inc. now owned by OrthoPediatrics Corp.)
- Secondary predicate: Affixus Tibial Nailing System
  (K150867, Biomet Incorporated, now owned by Zimmer Biomet)

IV. Device Description

The Pediatric Nailing Platform | Tibia offers a selection of rigid intramedullary nails for internal stabilization of the tibia. When a tibia is broken into multiple pieces, via a traumatic fracture(s), disease, or planned osteotomy(ies), alignment and stabilization of the bone fragments is critical to ensuring successful healing. When inserted down the intramedullary canal and locked with screws both proximally and distally, a rigid metallic nail provides resistance to bending and axial loading of the bone. In cases where compression is desired to stimulate bone regeneration, a dynamization slot can be utilized. End caps may be implanted with the nail, to ease removal by protecting the proximal threads of the nail and prevent bony ingrowth, as well preventing incarceration of the nail. All implants are single use and are made of Ti-6Al-4V ELI. The system is implanted using Class II and Class I exempt instruments. All implants and instruments in the system are provided non-sterile.

V. Indications for Use

Pediatric Nailing Platform | Tibia is intended as a temporary implant for alignment, stabilization and fixation of tibias that have been surgically prepared (osteotomy) for correction of deformities or have sustained fracture due to trauma or disease. The patient population is pediatric, including child and adolescent subgroups, and small-stature adults - such as patient with small intramedullary canals affected by skeletal dysplasias, osteogenesis imperfecta or other bone diseases. Nail lengths greater than 400mm are for skeletally mature patients.

VI. Comparison of Technological Characteristics

The subject device Pediatric Nailing Platform | Tibia and the previously cleared predicate device Simple Locking Intramedullary (SLIM) System (K192710) are substantially equivalent in that these devices share the same intended use, principles of operation, same patient population when used in deformity correction and fracture fixation of the tibia, and many fundamental technological characteristics. There are some differences between the predicate and subject devices in terms of system components, dimensions, materials, and MR safety labeling. The performance data provided in this submission supported that the differences between the subject and predicate devices do not raise different questions for safety and effectiveness.

VII. Performance Data

The Biocompatibility assessment and testing for the Pediatric Nailing Platform | Tibia were performed in conformance with ISO 10993-1. The implants of Pediatric Nailing Platform | Tibia were evaluated for use in an MR Environment and were determined to be MR Conditional. Performance testing according to ASTM F1264 and ASTM F543 was conducted to demonstrate that the Pediatric Nailing Platform | Tibia meets the design input requirements identified based

on the intended use of the device, including the needs of the user and patient, and where appropriate, applicable standards.

VIII. Conclusion

The information provided above supports that the Pediatric Nailing Platform | Tibia is as safe and effective as the predicate devices. Information and data provided within the submission support the differences between the subject and predicate devices do not raise different questions for safety and effectiveness. Therefore, it is concluded that the Pediatric Nailing Platform | Tibia is substantially equivalent to the predicate devices.

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