April 1, 2025

OrthoPediatrics Corp.
Yan Li
Regulatory Affairs Director
2850 Frontier Dr.
Warsaw, Indiana 46582

Re: K250623
Trade/Device Name: Pediatric Nailing Platform | Tibia Pediatric Nailing Platform | Femur
Regulation Number: 21 CFR 888.3020
Regulation Name: Intramedullary fixation rod
Regulatory Class: Class II
Product Code: HSB
Dated: February 28, 2025
Received: March 3, 2025

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Joseph P. Russell -S

Digitally signed by Joseph P. Russell -S
Date: 2025.04.01 14:37:36 -04'00'

for: Farzana Sharmin, PhD
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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K250623

Please provide the device trade name(s).

Pediatric Nailing Platform | Tibia
Pediatric Nailing Platform | Femur

Please provide your Indications for Use below.

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 and includes 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.

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Pediatric Nailing Platform | Femur is used for pediatric and small stature adult patients as indicated to stabilize fractures of the femoral shaft; subtrochanteric fractures; ipsilateral neck/shaft fractures; prophylactic nailing of impending pathologic fractures; nonunions and malunions; fixation of femurs that have been surgically prepared (osteotomy) for correction of deformity. Additional indications include simple long bone fractures; severely comminuted, spiral, large oblique and segmental fractures; polytrauma and multiple fractures; reconstruction, following tumor resection and grafting; supracondylar fractures; bone lengthening and shortening; fixation of fractures that occur in and between the proximal and distal third of the long bones being treated. The OrthoPediatrics' Pediatric Nailing Platform | Femur is for single use only.

Please select the types of uses (select one or both, as applicable).

- ☒ Prescription Use (Part 21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)
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510(k) Summary

I. Submitter

Submission:	Special 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:	April 1, 2025

II. Device

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

III. Predicate Device (Primary and Additional)

Substantial equivalence is claimed to the following predicate devices:

Subject Device	Predicate Device (Primary / Additional)
Pediatric Nailing Platform | Tibia	Pediatric Nailing Platform | Tibia - Cleared under K231266 - OrthoPediatrics Corp
Pediatric Nailing Platform | Femur	Pediatric Nailing Platform | Femur - Cleared under K220679 and K172583 - OrthoPediatrics Corp.

IV. Device Description

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 Pediatric Nailing Platform | Tibia was evaluated for use in an MR Environment and were determined to be MR Conditional. The system is implanted using Class II and Class I exempt instruments.

Pediatric Nailing Platform | Femur includes 316L stainless steel nails which are intended to be inserted into the medullary canal of the femur for fixation of fractures by aligning and stabilizing the bone fragments in small statue adults and pediatric populations. The nails have holes at each end which allow 316L stainless steel transverse screws to be installed to achieve greater stabilization. Pediatric Nailing Platform | Femur also offers end caps which are used to cap the head of the nail to prevent bony ingrowth and ease removal of the nail. The Pediatric Nailing Platform | Femur was evaluated for use in an MR Environment and were determined to be MR Conditional. The system is implanted using Class II and Class I exempt instruments.

V. Indications for Use

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.

Pediatric Nailing Platform | Femur is used for pediatric and small stature adult patients as indicated to stabilize fractures of the femoral shaft; subtrochanteric fractures; ipsilateral neck/shaft fractures; prophylactic nailing of impending pathologic fractures; nonunions and malunions; fixation of femurs that have been surgically prepared (osteotomy) for correction of deformity. Additional indications include simple long bone fractures; severely comminuted, spiral, large oblique and segmental fractures; polytrauma and multiple fractures; reconstruction, following tumor resection and grafting; supracondylar fractures; bone lengthening and shortening; fixation of fractures that occur in and between the proximal and distal third of the long bones being treated. The OrthoPediatrics' Pediatric Nailing Platform | Femur is for single use only.

VI. Comparison of Technological Characteristics

Pediatric Nailing Platform | Tibia is substantially equivalent to the predicate devices in Pediatric Nailing Platform | Tibia (K231266) in that these devices share identical intended use, patient population, principles of operation, and all fundamental technological characteristics.

Pediatric Nailing Platform | Femur is substantially equivalent to the predicate devices in Pediatric Nailing Platform | Femur (K220679 and K172583) in that these devices share identical intended use, patient population, principles of operation, and all fundamental technological characteristics.

The only differences between the subject and predicate devices are that the predicate devices are provided non-sterile without a shelf life and provided in cases and trays, while the subject device is provided sterile with 5 shelf life and provided in inner and outer pouches and shelf carton.

VII. Performance Data

The sterility, shelf life as well as the packaging of the subject sterile devices were supported by the sterilization validation and the packaging validation which includes aging and simulated transport.

An engineering analysis has been conducted that there is no impact of sterilization or aging on the products' performance and functionality.

The biocompatibility of the non-sterile predicate devices was assessed and cleared under previous 510(k)s. A biocompatibility assessment has been conducted and upon review of all available information regarding the devices and proposed new packaging materials, including how the device and packaging materials may be impacted by the updated cleaning, packaging, and sterilization flow, no further biocompatibility testing is deemed necessary.

There is no impact to the MR safety and subject devices remain MR conditional.

VIII. Conclusion

The information and data provided within the submission support that the Pediatric Nailing Platform / Tibia and Pediatric Nailing Platform / Femur are substantially equivalent to the predicate device.