July 20, 2022

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

Re: K220679
Trade/Device Name: Pediatric Nailing Platform | Femur
Regulation Number: 21 CFR 888.3020
Regulation Name: Intramedullary fixation rod
Regulatory Class: Class II
Product Code: HSB
Dated: June 14, 2022
Received: June 17, 2022

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,

Jiping Chen, MD, PhD, MPH
Acting 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)*
K220679

Device Name
Pediatric Nailing Platform | Femur

Indications for Use *(Describe)*
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 malunion; 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.

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

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:	March 4, 2022

II. Device

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

III. Predicate Device

Substantial equivalence is claimed to the following predicate devices:

Predicate Device:

- PediNail Intramedullary Platform, K172583, OrthoPediatrics Corp.

Note: PediNail Intramedullary Platform (K172583) has been marketed as Pediatric Nailing Platform | Femur System since the clearance of the sterile packed implants under K190321.

Reference Device:

- PediNail Intramedullary Nailing System, K083726, OrthoPediatrics Corp.

IV. Device Description

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 are provided as child

nails and adolescent nails. The child nails are available in diameters of 7, 8 and 9 mm with a length of 200 to 420 mm depending on the diameter. The adolescent nails are available in diameters of 9, 10, 11, 12 mm with a length of 280 to 500 mm depending on the diameter. The nails have holes at each end which allow 316L stainless steel transverse screws to be installed to achieve greater stabilization. The screws are available in 3.8, 4.0, 4.5 and 5.0 mm in diameter and 15-120 mm in length depending on the diameter. The end caps 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 Pediatric Nailing Platform | Femur system is implanted using class II and class I exempt instruments.

The subject implants under this submission in the Pediatric Nailing Platform | Femur are for single use only and will be provided non-sterile. The class II and class I exempt instruments can be single use or reusable and they are also provided non-sterile. All class II instruments have been cleared under K172583. The devices must be sterilized by the end user before use.

V. Indications for Use

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 malunion; 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

The OrthoPediatrics Pediatric Nailing Platform | Femur and predicate devices share identical indications for use. The Pediatric Nailing Platform | Femur and the predicate devices also share the same principles of operation in the same anatomical sites, materials of construction, body contact and duration of contact, sterilization, packaging, design and fundamental technological characteristics.

The purpose of this submission is to obtain clearance of longer adolescent nails, longer fully threaded and partially threaded screws, and new 4.0 mm fully threaded screws to be added to the existing nails and screws cleared under Pediatric Nailing Platform | Femur (K172583). This submission is also to obtain clearance of new end caps which have a retaining function comparing with the end caps cleared under K172583. The longer adolescent nails do not impact the intended use or disease state. Rather, the longer adolescent nail options ensure the scope of Pediatric Nailing Platform | Femur adolescent nails covers a wider range of patient anatomy and matches competitor's offerings. Similarly, the addition of longer length options for 4.5 mm and 5.0 mm

fully threaded screws and partially threaded screws and a dedicated 4.0 mm fully threaded screw will ensure that a wider range of patient anatomy is addressable within the system. The subject and predicate end caps share the exact same dimensions and intended use which is to cap the head of the nail to prevent bony ingrowth and ease removal of the nail. Performance testing has been conducted to support the differences between the subject and predicate device and to establish the substantial equivalence.

VII. Performance Data

Verification testing (Torsional Performance & Driving Torque, Axial Pullout, Bending Strength and Full Construct) was conducted to demonstrate that the new nails and screws added to the Pediatric Nailing Platform | Femur (K172583) meet 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.

The subject devices to be added to the Pediatric Nailing Platform | Femur system (K172583) were evaluated for use in an MR Environment for the below requirements and were determined to be MR Conditional.

The Pediatric Nailing Platform | Femur System in its final finished form is identical to Pediatric Nailing Platform | Femur System (previously marketed device, cleared under K172583) in formulation, processing, sterilization, and geometry and no other chemicals have been added (e.g., plasticizers, fillers, additives, cleaning agents, mold release agents).

VIII. Conclusion

The information provided above supports that the Pediatric Nailing Platform | Femur 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. Therefore, it is concluded that the Pediatric Nailing Platform | Femur is substantially equivalent to the predicate devices.

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