



September 24, 2026

OrthoPediatics Corp.
Jessica Powers
Senior Regulatory Affairs Specialist
2850 Frontier Dr.
Warsaw, Indiana 46582

Re: K261345
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: August 28, 2026
Received: August 28, 2026

Dear Jessica Powers:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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,

FARZANA SHARMIN -S

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.

K261345

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Please provide the device trade name(s).

?

Pediatric Nailing Platform | Femur

Please provide your Indications for Use below.

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The Pediatric Nailing Platform | Femur is used for pediatric and small stature adult patients as indicated to stabilize fractures of the femoral shaft; prophylactic nailing of impending pathologic fractures; nonunions and malunions; fixation of femurs that have been surgically prepared (osteotomy) for correction of deformity; 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.

Additional indications of the Pediatric Nailing Platform | Femur Antegrade nails include subtrochanteric fractures and ipsilateral neck/shaft fractures.

The Pediatric Nailing Platform | Femur is for single use only.

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

- ☒ Prescription Use ([21 CFR 801 Subpart D](#))
☐ Over-The-Counter Use ([21 CFR 801 Subpart C](#))

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Please select the age group(s) for which the device(s) is to be used.

- ☐ Neonates/Newborns (Birth to < 29 days old)
☐ Infants (29 days old to < 2 years old)
☒ Children (2 years old to < 12 years old)
☒ Adolescents (12 years old to < 22 years old)
☒ Adults (22 years old and greater)

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510(k) Summary

I. Submitter

Submission:	Traditional 510(k) Premarket Notification
Applicant:	OrthoPediatics Corp.
Applicant Address:	2850 Frontier Drive, Warsaw, IN 46582
Establishment Registration Number:	3006460162
Contact:	Jessica Powers
Contact Phone:	(574) 268-6379
Date Prepared:	September 23, 2026

II. Device

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

III. Predicate Device and Reference Device

Primary Predicate Device:

Pediatric Nailing Platform | Femur

- OrthoPediatics Corp., cleared under K250623, K220679 and K172583

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

Secondary Predicate Device:

DePuy Synthes Retrograde Femoral Nail Advanced System

- DePuy Synthes, cleared under K233696 and K201346

Reference Device:

The Simple Locking Intramedullary (Slim) System

- Pega Medical Inc., now owned by OrthoPediatics Corp., cleared under K192710

IV. Device Description

The Pediatric Nailing Platform | Femur consists of a family of nails, screws, end caps, and condylar nuts available in 316L stainless steel or Ti-6Al-4V ELI titanium alloy. The nails are available in both antegrade



and retrograde configurations and 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 stature adults and pediatric populations. The nails include holes at each end to accommodate screws, providing additional stabilization. Optional condylar nuts are also available for use with the system. In addition, the system offers end caps designed to cover the nail head, helping prevent bony ingrowth and facilitating easier nail removal. The Pediatric Nailing Platform | Femur was evaluated for use in an MR environment and 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 | Femur is used for pediatric and small stature adult patients as indicated to stabilize fractures of the femoral shaft; prophylactic nailing of impending pathologic fractures; nonunions and malunions; fixation of femurs that have been surgically prepared (osteotomy) for correction of deformity; 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.

Additional indications of the Pediatric Nailing Platform | Femur Antegrade nails include subtrochanteric fractures and ipsilateral neck/shaft fractures.

The Pediatric Nailing Platform | Femur is for single use only.

VI. Comparison of Technological Characteristics

The subject Pediatric Nailing Platform | Femur devices are substantially equivalent to the predicate Pediatric Nailing Platform | Femur (K250623) devices in that these devices have the same intended use, principle of operation, many other similar fundamental technological characteristics. There are some technological differences between the subject devices, however, those differences are supported by non-clinical testing provided in this submission. Accordingly, these differences do not raise different questions of safety or effectiveness.

VII. Performance Data

The sterilization, packaging and shelf life of the subject devices were supported by the following verification and validation activities:

- **Sterilization and Cleaning Validation** following AAMI ST72, AAMI ST98, ASTM F3127, ISO 11137-1, ISO 11137-2, ISO 11737-1, ISO 11737-2, ISO 11737-3 and ISO 19227.
- **Package Design Verification** following ASTM D4332, ASTM D4169, ASTM F2096, ASTM F2203, ASTM F88, ASTM F1886, ISO 11607-1, ISO 11607-2 and ISO 15415/15416.
- **Shelf Life Validation** following ASTM F1980, ASTM F1886, ASTM F2096, ASTM F2203, ASTM F88, ISO 11607-1, ISO 11607-2 and ISO 15415/15416.
- **Usability Validation** following ISO 11607-1 and IEC-62366-1

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



The biocompatibility assessment for the Pediatric Nailing Platform Femur titanium implants subject to this submission was conducted in accordance with ISO 10993-1 and was based on the prior use of the OrthoPediatrics Corp's Pediatric Nailing Platform|Tibia (K231266, K250623) which share the same materials, same manufacturing and cleaning processes, same geometry and physical properties, as well as same body contact and clinical use.

The implants of Pediatric Nailing Platform|Femur were evaluated for use in an MR environment using ASTM F2052, ASTM F2213, ASTM F2182, and ASTM F2119, and were determined to be MR Conditional and will be labeled as such.

Mechanical performance evaluations included Torsional Properties, Insertion and Removal Torque, Axial Pullout Strength per ASTM F543 and Static Four-Point Bending, Static Torsion and Bending Fatigue per ASTM F1264. Results of the mechanical testing demonstrate substantially equivalent mechanical performance of the subject device as compared to the predicate.

Results of the performance testing demonstrate substantially equivalent performance of the subject device as compared to the predicate.

VIII. Conclusion

The Information and data provided within the submission support that the Pediatric Nailing Platform|Femur is substantially equivalent to the predicate device.