April 30, 2026

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

Re: K260323
Trade/Device Name: OrthoPediatrics® Locking Cannulated Blade Plate System
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/Multiple Component Metallic Bone Fixation Appliances And Accessories
Regulatory Class: Class II
Product Code: HRS, HWC
Dated: January 30, 2026
Received: January 30, 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,

CHRISTOPHER FERREIRA -S

Christopher Ferreira, M.S.
Assistant Director
DHT6C: Division of Restorative,
Repair, and Trauma 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.	K260323

Please provide the device trade name(s).

OrthoPediatrics® Locking Cannulated Blade Plate System

Please provide your Indications for Use below.

The OrthoPediatrics Locking Cannulated Blade Plate System is intended for fixation of long bone fractures and osteotomies in all pediatric subgroups (except neonates) and in small stature adults. Specific indications include: intertrochanteric derotation and varus osteotomies, femoral neck and pertrochanteric fractures, intertrochanteric valgus osteotomies, proximal and distal tibial osteotomies and humeral fractures and osteotomies.

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)

K260323
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:	Jessica Powers
Contact Phone:	(574) 268-6379
Date Prepared:	January 30, 2026

II. Device

Device Trade Name:	OrthoPediatrics® Locking Cannulated Blade Plate System
Common Name:	Bone Plates and Bone Screws
Regulation Number:	21 CFR 888.3030
	21 CFR 888.3040
Device Classification Name:	Single/multiple component metallic bone fixation appliances and accessories
	Smooth or threaded metallic bone fixation fastener
Product Code:	HRS: Plate, Fixation, Bone
	HWC: Screw, Fixation, Bone
Device Classification:	II
Classification Panel:	Orthopedic

III. Predicate Device and Reference Device

Primary Predicate Device:

OrthoPediatrics Blade Plate System

- OrthoPediatrics Corp., cleared under K110959

Reference Device:

Pediatric Plating Platform Hip

- OrthoPediatrics Corp., cleared under K243963

Pediatric Nailing Platform | Tibia and Pediatric Nailing Platform | Femur

- OrthoPediatrics Corp., cleared under K250623

PediFlex™ Flexible Nail System

- OrthoPediatrics Corp., cleared under K251362

IV. Device Description

The OrthoPedatrics Locking Cannulated Blade Plate System combines implants and instruments in one convenient system and offers the advantages of the osteotomy blade plates and cannulated instrumentation. Osteotomy plates with dynamic compression slots aid in reduction and rotational stability while maintaining bone stock. Cannulated instruments work over a guide wire for targeted placement.

The system is offered in three size ranges – infant, child, and adolescent. Each offers the ability to insert a locking or nonlocking screw into femoral neck to dynamically compress the fracture and osteotomy sites to create a stable construct.

Cortical screws are offered in two diameters—3.5 mm and 4.5 mm—and are available in both locking and non-locking configurations for plate fixation. Additionally, the system includes a comprehensive set of surgical instruments designed to facilitate implant placement.

The implants of the OrthoPediatrics Locking Cannulated Blade Plate System are manufactured from implant grade stainless steel conforming to ASTM F138.

The locking cannulated blade plates in the OrthoPediatrics Locking Cannulated Blade Plate System are offered sterile and non-sterile. All other Class II implants and Class I, exempt instruments of the OrthoPediatrics Locking Cannulated Blade Plate System are offered non-sterile to be sterilized by the end user.

V. Indications for Use

The OrthoPediatrics Locking Cannulated Blade Plate System is intended for fixation of long bone fractures and osteotomies in all pediatric subgroups (except neonates) and in small stature adults. Specific indications include intertrochanteric derotation and varus osteotomies, femoral neck and pertrochanteric fractures, intertrochanteric valgus osteotomies, proximal and distal tibial osteotomies and humeral fractures and osteotomies.

VI. Comparison of Technological Characteristics

The subject OrthoPediatrics Locking Cannulated Blade Plate System devices are substantially equivalent to the predicate OrthoPedatrics Blade Plate System (K110959) devices in that these devices share identical intended use, patient population, principles of operation, and all fundamental technological characteristics. There are some differences between the predicate and subject devices in terms of sterilization, packaging, shelf life, and MR labeling. However, those differences are supported by successful testing provided in this submission. Therefore, such differences do not raise new questions of safety and 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 of the non-sterile predicate devices was previously assessed and cleared under K110959. 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.

The implants of the OrthoPediatrics Locking Cannulated Blade Plate System have been evaluated for use in an MR environment in following ASTM F2052, ASTM F2213, ASTM F2182, ASTM F2119, and FDA guidance "*Testing and Labeling Medical Devices for Safety in the Magnetic Resonance (MR) Environment - Guidance for Industry and Food and Drug Administration Staff*" issued on October 10, 2023. The implants were determined to be MR Conditional and will be labeled as such.

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 OrthoPediatrics Locking Cannulated Blade Plate System is substantially equivalent to the predicate device.