June 24, 2025

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

Re: K251362
Trade/Device Name: PediFlex™ Flexible Nail System
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth Or Threaded Metallic Bone Fixation Fastener
Regulatory Class: Class II
Product Code: HTY
Dated: April 30, 2025
Received: May 1, 2025

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 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,

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K251362

Device Name
PediFlex™ Flexible Nail System

Indications for Use *(Describe)*
The PediFlex™ Flexible Nail System is intended for fixation of diaphyseal fractures of long bones where the medullary canal is narrow, or flexibility of the implant is required. This includes upper extremity fractures in all patients and lower extremity fractures in pediatric or small stature patients. In pediatric patients, the flexibility of the nail allows it to be inserted at a point that does not disturb or disrupt the growth plate.

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:	Jessica Powers
Contact Phone:	(574) 268-6379
Date Prepared:	June 23, 2025

II. Device

Device Trade Name:	PediFlex™ Flexible Nail System
Common Name:	Intramedullary Nails and Accessories
Regulation Number:	21 CFR 888.3040
Device Classification Name:	Smooth or threaded metallic bone fixation fastener
Product Code:	HTY: pin, fixation, smooth
Device Classification:	II
Classification Panel:	Orthopedic

III. Predicate Device and Reference Device

Substantial equivalence is claimed to the following predicate devices:

Primary Predicate Device:

- PediFlex™ Flexible Nail System (K201838, OrthoPediatrics Corp.)

IV. Device Description

The PediFlex™ Flexible Nail System includes stainless steel and titanium flexible nails, interlocking clamps, clamp screws and end caps for the application of aiding bone fracture repair and healing. All the implants are MR conditional. The system is implanted using Class II and Class I exempt surgical instruments.

The PediFlex™ flexible nails are provided in 316L stainless steel and titanium alloy (Ti-6Al-4V). The 316L stainless steel flexible nails are available in diameters ranging from 1.5 mm to 4.0 mm in increments of 0.5 mm. The titanium alloy (Ti-6Al-4V) flexible nails are available in diameters ranging from 1.5 mm to 4.5 mm in increments of 0.5 mm.

The PediFlex™ interlocking clamps are designed to hold flexible nails in place after insertion by clamping the nail and being fixed to the bone. The use of the interlocking clamps is optional. The interlocking

clamps are manufactured from both 316L stainless steel and titanium alloy (Ti-6Al-4V) materials. The 316L stainless steel interlocking clamps are available in right and left configurations, in diameters of 3.0 mm, 3.5 mm and 4.0 mm which are to be used with 316L stainless steel flexible nails in diameters of 3.0 mm, 3.5 mm and 4.0 mm. The 316L stainless steel clamp screws are available in 15 mm, 25 mm, and 35 mm in length. The titanium alloy (Ti-6Al-4V) interlocking clamps are available in right and left configurations, in diameters of 3.0 mm, 3.5 mm, 4.0 mm and 4.5 mm which are to be used with titanium alloy (Ti-6Al-4V) flexible nails in diameters of 3.0 mm, 3.5 mm, 4.0 mm and 4.5 mm. The titanium alloy (Ti-6Al- 4V) clamp screws are available in 15 mm, 25 mm, and 35 mm in length. The material of the clamp must match the material of the nail and screw in the surgery.

The PediFlex™ end caps are designed to affix to the exposed nail tip to help prevent soft tissue irritation. The use of the end cap is optional. They are not a structural element and impart no additional strength to the construct. The subject end caps are manufactured in titanium alloy (Ti-6Al-4V) and are available in diameters ranging from 1.5mm to 4.5mm with 0.5mm increments which are to be used with titanium alloy (Ti-6Al-4V) flexible nails in diameters ranging from 1.5mm to 4.5mm with 0.5mm increments. The material of the end cap must match the material of the nail used in the surgery.

The flexible nails, interlocking clamps, clamp screws and end caps in PediFlex™ Flexible Nail System are offered both sterile and non-sterile. All other Class II implants and instruments of the PediFlex™ Flexible Nail System are offered non-sterile to be sterilized by the end-user.

V. Indications for Use

The PediFlex™ Flexible Nail System is intended for fixation of diaphyseal fractures of long bones where the medullary canal is narrow, or flexibility of the implant is required. This includes upper extremity fractures in all patients and lower extremity fractures in pediatric or small stature patients. In pediatric patients, the flexibility of the nail allows it to be inserted at a point that does not disturb or disrupt the growth plate.

VI. Comparison of Technological Characteristics

The subject PediFlex™ Flexible Nail System and predicate device 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 conditional 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 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.

The implants of the PediFlex™ Flexible Nail 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 PediFlex™ Flexible Nail System is substantially equivalent to the predicate device.