29 January 2021

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

Re: K201838
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: December 21, 2020
Received: December 23, 2020

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,

For Colin O'Neill, M.B.E.
Assistant Director
DHT6B: Division of Spinal 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)*

K201838

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:** | Yan Li |
| **Contact Phone:** | (574) 267-0864 |
| **Date Prepared:** | January 28, 2021 |

## II. Device

| | |
|---|---|
| **Device Trade Name:** | PediFlex™ Flexible Nail System |
| **Regulation Number:** | 21 CFR 888.3040 |
| **Product Code:** | HTY |
| **Device Classification:** | II |
| **Common Name:** | Pin, Fixation, Smooth |
| **Classification Panel:** | Orthopedic |

## III. Predicate Device

Substantial equivalence is claimed to the following predicate devices:

**Primary predicate:**

- Orthopediatrics PediFlex™ Flexible Nail System, K082375, OrthoPediatrics Corp.

**Secondary predicate:**

- Orthopediatrics PediFlex™ Flexible Nail System, K081097, OrthoPediatrics Corp.

## IV. Device Description

The PediFlex™ Flexible Nail System includes stainless steel and titanium flexible nails, interlocking clamps, and clamp screws for the application of aiding bone fracture repair and healing. The PediFlex™ Flexible Nail System 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.

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 tip of the flexible nails is available in two designs, the round tip and the advanced round tip. Both tip designs are provided in 316L stainless steel and titanium alloy (Ti-6Al-4V) in various diameters and lengths.
The PediFlex™ interlocking clamps are designed to hold flexible nails in place after insertion by clamping the nail and being fixed to the bone. Using the interlocking Clamps is optional in the surgery. 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 system is implanted using Class II and Class I exempt instruments. The Class II instruments in the system include hex drivers which are for installing the clamp screws and the hex easy out which is to remove the clamp screws if the hex strips. The rest of the instruments in the system are Class I exempt.

The implants in the PediFlex™ Flexible Nail System are for single use only and will be provided non-sterile. The instruments in the PediFlex™ Flexible Nail System are reusable, except for the Hex Easy Out instrument which is single use. Instruments are also provided non-sterile. The devices must be sterilized by the end user before use.

## 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 PediFlex™ Flexible Nail System and predicate devices share identical indications for use, which 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.

The PediFlex™ Flexible Nail System 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, and fundamental technological characteristics; and they have similar dimensions and design features for implants and instruments and components types.

The modifications to the nail tip design for the stainless steel and titanium flexible nails in the PediFlex™ Flexible Nail System are line extensions of the flexible nails in the PediFlex™ Flexible Nail System cleared in K081097 and K082375. They have same materials of construct, dimensions, principal of operation and the only difference is the tip design. which does not create a new worst case or affect the strength of the implant. Therefore, these minor differences in tip design do not raise new questions of safety or effectiveness.

Components introduced in this submission include the interlocking clamps and clamp screws. The clamp and clamp screws are designed to hold flexible nails in place after insertion by clamping the nail and being fixed to the bone. Using the interlocking clamps is optional in the surgery. Successful performance testing has been conducted on the clamps and clamp screws to demonstrate their substantial equivalence.

The predicate devices have not been evaluated in an MR environment. The subject device PediFlex™ Flexible Nail System was evaluated for use in an MR Environment and was determined to be MR Conditional.

## VII. Performance Data

Performance testing was conducted to demonstrate that the PediFlex™ Flexible Nail System meets 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 following performance data is provided in support of the substantial equivalence determination:

Verification Testing:

- VerRep-1001-0003 PediFlex ILC Construct Test
- VerRep-1001-0009 ILC ASTM F543

Validation Testing:

- ValRep-1001-0001 PediFlex Advanced Validation
- ValRep-1001-0004 PediFlex ILC Validation
- ValRep-1001-0008 PediFlex ILC Usability

The PediFlex™ Flexible Nail System implants were evaluated for use in an MR Environment and were determined to be MR Conditional. The following testing data were provided in support of MR compatibility.

- MRER-1001-001 PediFlex Advanced MRER
- VerRep-9999-0007 MR Compatibility – Force and Torque
- VerRep-9999-0008 MR Compatibility – Artifact Testing
- VerRep-9999-0014 MR Heating – PediFlex

Biocompatibility testing for the PediFlex™ Flexible Nail System was performed in conformance with ISO 10993-1. The following test reports are provided to support the biocompatibility of the subject devices.

- VerRep-0999-0006 Solid IM Nails Biocompatibility
- VerRep-0999-0009 Instrument Biocompatibility

A list of FDA recognized standards used for the evaluation of the performance of the devices have been listed in the table.

| **FDA Recognition Number** | **Standard Reference** | **Standard Title** |
|---|---|---|
| 11-327 | ASTM F543-17 | Standard Specification and Test Methods for Metallic Medical Bone Screws |
| 8-422 | ASTM F2052-15 | Standard Test Method for Measurement of Magnetically Induced Displacement Force on Medical Devices in the Magnetic Resonance Environment |
| 8-153 | ASTM F2119-07/(R)2013 | Standard Test Method for Evaluation of MR Image Artifacts from Passive Implants |
| 8-227 | ASTM F2182-11a | Standard Test Method for Measurement of Radio Frequency Induced Heating on or Near Passive Implants During Magnetic Resonance Imaging |
| 8-466 | ASTM F2213-17 | Standard Test Method for Measurement of Magnetically Induced Torque on Medical Devices in the Magnetic Resonance Environment |
| 5-114 | ANSI AAMI IEC 62366-1:2015 | Medical Devices – Application of usability engineering to medical devices |
| 2-220 | ANSI AAMI ISO 10993-1:2018 | Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process (ISO 10993-1:2009) |
| 2-245 | ANSI AAMI ISO 10993-5:2009/(R)2014 | Biological evaluation of medical devices – Part 5: Tests for in vitro cytotoxicity |

| FDA Recognition Number | Standard Reference | Standard Title |
|---|---|---|
| 2-174 | ANSI AAMI ISO 10993-10: 2010/(R)2014 | Biological evaluation of medical devices – Part 10: Tests for irritation and skin sensitization |
| 2-237 | ANSI AAMI ISO 10993-17: 2002/(R)2012 | Biological evaluation of medical devices. Establishment of allowable limits for leachable substances |

## VIII. Conclusion

The information provided above supports that the PediFlex™ Flexible Nail System is substantially equivalent to 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 PediFlex™ Flexible Nail System is substantially equivalent to the predicate devices.