October 09, 2019

OrthoPediatrics, Corp.
Jen Gregory
Regulatory Affairs Manager
2850 Frontier Drive
Warsaw, Indiana 46582

Re: K190321
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: September 9, 2019
Received: September 10, 2019

Dear Jen Gregory:

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,

Michael Owens
Acting 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

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)*
K190321

Device Name
Pediatric Nailing Platform|Femur

Indications for Use *(Describe)*
The OrthoPediatrics 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 malunions; fixation of femurs that have been surgically prepared (osteotomy) for correction of deformity.

Additional indications includes 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

In accordance with 21 CFR §807.92 and the Safe Medical Devices Act of 1990, the following information is provided for the OrthoPediatrics Pediatric Nailing Platform|Femur 510(k) premarket notification. The submission was prepared in accordance with the FDA guidance document, 'Format for Traditional and Abbreviated 510(k)s', issued on August 12, 2005.

Sponsor: OrthoPediatrics, Corp.
2850 Frontier Drive
Warsaw, IN 46582
Establishment Registration Number: 3006460162
Phone: (574) 267-6379
Fax: (574) 269-3692

Contact: Jennifer Gregory
Regulatory Affairs Manager

Date: September 6, 2019

Subject Device: Trade Name: OrthoPediatrics Pediatric Nailing Platform|Femur

Regulation Number: 888.3020

Regulation Name: Intramedullary fixation rod

Product Code: HSB

Common Name: Rod, Fixation, Intramedullary and Accessories

Legally marketed devices to which substantial equivalence is claimed:

- K172583 – OrthoPediatrics' PediNail Intramedulary Nailing System

Device Description

The predicate OrthoPediatrics PediNail Intramedullary Platform (K172583) consists of rigid stainless steel nails and stainless steel screws. Both the cleared and subject devices are composed of the intramedullary fixation rods (nails) with screw holes at either end for fixation to bone, screws, interlocking pegs, and end caps coupled with device-specific instruments including the Modular Necks, the Targeting Guides, the Attachment Bolts, the Derotation Dial Targeting Guide Attachment, the AP Nail Positioning Jig, the AP Position Templates, the Impactors, and the Nail Extractor Adaptor.

The proposed OrthoPediatrics Pediatric Nailing Platform|Femur seeks to add sterile packaged nails for distribution. All subject components have previously been cleared as non-sterile implants. All other components of the OrthoPediatrics Pediatric Nailing Platform|Femur will remain non-sterile to be sterilized by end-user.

The OrthoPediatrics Pediatric Nailing Platform|Femur nails have a complex 3-dimensional geometry resulting in an anatomically appropriate design which with an advanced surgical technique. The smaller diameter of the nail allows it to be inserted in patients with a narrow medullary canal and allows for easier insertion without the need for excessive reaming.

The proposed nails are manufactured from stainless steel conforming to ASTM F138 and are available in child and adolescent configurations:

- The child nails are available in 7mm, 8mm, and 9mm diameters.
- The adolescent nails are available in 9mm, 10mm, 11mm, and 12mm diameters.
- These nails range in length from 20cm to 42cm, depending on the nail diameter.
- Surgeon preference dictates the appropriate nail size required to stabilize the fracture and allow for appropriate healing.

Intended Use and Indications for Use

The OrthoPediatrics 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 malunions; 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.

Summary of Technological Characteristics

The technological characteristics (materials, design, sizing) of the OrthoPediatrics Pediatric Nailing Platform|Femur are identical to the predicate OrthoPediatrics PediNail Intramedullary Nailing System (K172583).

The rationale for substantial equivalence is based on consideration of the following characteristics:

- **Intended Use:** The intended use is identical to the predicate (K172583).
- **Indications for Use:** Indications for Use are identical to the predicate (K172583).
- **Materials:** Materials are identical to the predicate (K172583).
- **Design Features:** Design features are identical to the predicate (K172583).
- **Function:** The function is identical to the predicate (K172583).
- **Sterilization:** The proposed OrthoPediatrics Pediatric Nailing Platform|Femur seeks to add sterile packaged nails for distribution. All subject components have previously been cleared as non-sterile implants. All other components will remain non-sterile to be sterilized by end-user.

Summary of Performance Data (Nonclinical and/or Clinical)

Performance Testing – Bench

No design changes have been made since previous submission. This submission relates only to sterilization of the Pediatric Nailing Platform|Femur nails.

- *Mechanical testing VerRep-1005-0004 provided objective evidence that there is no effect on mechanical properties of 316L stainless steel when exposed to a high dose of gamma radiation (75kGy).*

Therefore, no additional bench testing is required for or included in this submission.

Performance Testing – Animal

Not applicable. Animal testing was not necessary to determine substantial equivalence of the OrthoPediatrics Pediatric Nailing Platform|Femur.

Performance Testing – Clinical

Not applicable. Clinical testing was not necessary to determine substantial equivalence of the OrthoPediatrics Pediatric Nailing Platform|Femur.

Substantial Equivalence Conclusion

OrthoPediatrics believes that the Pediatric Nailing Platform|Femur is substantially equivalent to the legally marketed predicate, OrthoPediatrics PediNail Intramedullary Nailing System (K172583) based on the similarities of design, intended use, materials, sizing. Risk analysis and design control activities including verification activities were conducted to mitigate identified new risks associated with packaged sterile devices, and it is expected that the subject Pediatric Nailing Platform|Femur will perform substantially equivalent to the legally marketed predicate device.