



OrthoPediatics, Inc.
James L. Crumley II
Vice President Quality Assurance and Regulatory Affairs
2850 Frontier Drive
Warsaw, Indiana 46582

May 10, 2018

Re: K172583

Trade/Device Name: OrthoPediatics PediNail Intramedullary Platform
Regulation Number: 21 CFR 888.3020
Regulation Name: Intramedullary fixation rod
Regulatory Class: Class II
Product Code: HSB
Dated: May 4, 2018
Received: May 7, 2018

Dear James Crumley:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820);

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 <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (<https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/>) and CDRH Learn (<http://www.fda.gov/Training/CDRHLearn>). 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 (<http://www.fda.gov/DICE>) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Katherine D. Kavlock -S

for
Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K172583

Device Name

OrthoPediatrics PediNail Intramedullary Platform

Indications for Use (Describe)

The OrthoPediatrics PediNail Intramedullary Platform 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 malunion; 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 PediNail Intramedullary Platform 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 OrthoPediatics PediNail Intramedullary Platform 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: OrthoPediatics, Corp.
2850 Frontier Drive
Warsaw, IN 46582
Establishment Registration Number: 9102640
Phone: (574) 267-6379
Fax: (574) 269-3692

Contact: Jim Crumley
VP of Regulatory Affairs

Date: May 9, 2018

Subject Device: Trade Name: OrthoPediatics PediNail Intramedullary Platform

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:

- K083726 – OrthoPediatics PediNail Intramedullary Nailing System

Device Description

The OrthoPediatics PediNail Intramedullary Nailing System (K083726) consists of a rigid stainless steel nail and stainless steel screws. The proposed OrthoPediatics PediNail Intramedullary Platform seeks to broaden the reach of the PediNail brand by offering additional nail diameters, screws, nails designed specifically for child and adolescent, and improved instrumentation. The proposed device is 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 OrthoPediatics PediNail Intramedullary Platform nails have a complex 3-dimensional geometry resulting in an anatomically appropriate design. 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.

Intended Use and Indications for Use

The OrthoPediatics PediNail Intramedullary Platform 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 malunion; 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 OrthoPediatics PediNail Intramedullary Platform is for single use only.

Summary of Technological Characteristics

The technological characteristics (materials, design, sizing) of the OrthoPediatics PediNail Intramedullary Platform are similar to the predicate OrthoPediatics PediNail Intramedullary Nailing System (K083726).

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

- **Intended Use:** The proposed OrthoPediatics PediNail Intermedullary Platform 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; nonunion and malunion; fixation of femurs that have been surgically prepared (osteotomy) for correction of deformity which is identical to the predicate (K083726).
- **Indications for Use:** Indications for Use are identical to the predicate (K083726).
- **Materials:** The proposed OrthoPediatics PediNail Intramedullary Platform nails, screws, end caps, and pegs are manufactured from 316L stainless steel conforming to ASTM F138 which is identical to the material of the predicate (K083726).
- **Design Features:** The proposed OrthoPediatics PediNail Intramedullary Platform incorporate similar design features as the predicate (K083726).
- **Function:** OrthoPediatics PediNail Intramedullary Platform is used to address femoral shaft fractures, subtrochanteric femur fractures, ipsilateral neck/shaft fractures, prophylactic nailing of impending pathologic fractures, nonunions, malunions, and fixation of femurs that have been surgically prepared (osteotomy) for correction of deformity. This is identical to the predicate (K083726).
- **Sterilization:** The proposed OrthoPediatics PediNail Intramedullary Platform is provided non-sterile and requires sterilization prior to use which is the same sterilization method utilized for the predicate (K083726).

Summary of Performance Data (Nonclinical and/or Clinical)

- Non-Clinical Tests

Non-clinical, Static Four-Point Bend Testing, Static Torsion Testing, Torsional Yield Strength Testing, and Driving Torque Testing was performed comparing the proposed OrthoPediatrics PediNail Intramedullary Platform to the predicate OrthoPediatrics PediNail Intramedullary Nailing System (K083726). Testing concluded that the proposed OrthoPediatrics PediNail Intramedullary Platform will perform equivalently to the predicate OrthoPediatrics PediNail Intramedullary Nailing System.

Full construct testing was performed. The construct consisted of a 7mm nail (system worst case), locked distally with a single screw in the dynamic position of the slot (i.e. not at the top of the slot) and a length-stable transverse fracture/osteotomy located 3cm above the superior-most distal screw hole. 4th generation composite femur sawbones were used and load was applied through the femoral head to allow for all possible loads—axial compression, bending, and torsion.

Three such constructs survived 150,000 cycles at a load of 75kg (165lbs).

The survival of three constructs subjected to the above conditions demonstrates no additional risk is conferred to the device from the presence or use of the dynamic slot.

Based on the results of this testing, it is concluded that the proposed OrthoPediatrics PediNail Intramedullary Platform does not raise any new issues of safety and effectiveness and is substantially equivalent to the predicate OrthoPediatrics PediNail Intramedullary Nailing System (K083726).

- The OrthoPediatrics PediNail Intramedullary Platform was evaluated in an MR Environment and was determined to be MR Conditional.
- Clinical Tests
None provided as a basis for substantial equivalence.

Substantial Equivalence Conclusion

OrthoPediatrics believes that the proposed PediNail Intramedullary Platform is substantially equivalent to the legally marketed predicate, OrthoPediatrics PediNail Intramedullary Nailing System (K083726) based on the similarities of design, intended use, materials, sizing, and the results of verification activities conducted. No new risks have been identified and it is expected that the proposed OrthoPediatrics PediNail Intramedullary Platform will perform substantially equivalent to the legally marketed predicate device.