December 6, 2017
OrthoPediatrics, Inc.
Adam Cargill
Regulatory Affairs Manager
2850 Frontier Drive
Warsaw, Indiana 46582

Re: K172425
Trade/Device Name: OrthoPediatrics Wrist Fusion Plate
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/Multiple Component Metallic Bone Fixation Appliances And Accessories
Regulatory Class: Class II
Product Code: HRS
Dated: October 31, 2017
Received: November 2, 2017

Dear Adam Cargill:

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,

Vincent J. Devlin -S

for
Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K172425

Device Name
OrthoPediatrics Wrist Fusion Plates

Indications for Use *(Describe)*

OrthoPediatrics Wrist Fusion Plates are intended for wrist arthrodesis and fractures of other small bones in children, adolescents, and small stature adults. Specific indications include post-traumatic arthritis of the joints of the wrist; rheumatoid wrist deformities requiring restoration; complex carpal instability; post-septic arthritis of the wrist; severe unremitting pain related to motion; brachial plexus nerve palsies; tumor resection; and spastic deformities.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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In accordance with 21 CFR §807.92 and the Safe Medical Devices Act of 1990, the following information is provided for the OrthoPediatrics Wrist Fusion Plates 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: 9102640
Phone: (574) 267-6379
Fax: (574) 269-3692

Contact: Adam Cargill
Regulatory Affairs Manager

Date: December 6, 2017

Subject Device: Trade Name: OrthoPediatrics Wrist Fusion Plates

Regulation Number: 888.3030

Regulation Name: Single/multiple component metallic bone fixation appliances and accessories

Product Code: HRS

Common Name: Plate, Fixation, Bone

Legally marketed devices to which substantial equivalence is claimed:

- K042355 – Synthes LCP Wrist Fusion Plates
- K093474 – DePuy Fracture and Fusion Plating System

Device Description

OrthoPediatrics Wrist Fusion Plates are provided non-sterile, are available in two lengths, 99mm and 112mm, to accommodate a patient with or without a Proximal Row Carpectomy (PRC). The Wrist Fusion Plates accept 2.7mm screws both distally and in the capitate, and 3.5mm screws proximally. These screws were previously cleared in the PediLoc Fragment System 510(k), K140431. In additional to the two wrist fusion plates, bending templates are included to assist with intra-operative contouring of the plate into either dorsiflexion or palmar flexion.

Intended Use and Indications for Use

OrthoPediatrics Wrist Fusion Plates are intended for wrist arthrodesis and fractures of other small bones in children, adolescents, and small stature adults. Specific indications include post-traumatic arthritis of the joints of the wrist; rheumatoid wrist deformities requiring restoration; complex carpal instability;

post-septic arthritis of the wrist; severe unremitting pain related to motion; brachial plexus nerve palsies; tumor resection; and spastic deformities.

Summary of Technological Characteristics

The technological characteristics (materials, design, sizing, and indications) of the OrthoPediatrics Wrist Fusion Plates are similar to the predicate Synthes LCP Wrist Fusion Plates (K042355).

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

- **Intended Use:** The proposed OrthoPediatrics Wrist Fusion Plates are intended for wrist arthrodesis and fractures of other small bones which is identical to the predicate (K042355).
- **Indications for Use:** Indications for Use are identical to the predicate (K042355).
- **Materials:** The proposed OrthoPediatrics Wrist Fusion Plates are manufactured from 316L stainless steel conforming to ASTM F138/ASTM F139 which is similar to the material of the predicate (K042355).
- **Design Features:** The proposed OrthoPediatrics Wrist Fusion Plates incorporate similar design features as the predicate (K042355). This includes accepting 2.7mm screws distally and 3.5mm screws proximally, and a low-profile plate with tapered ends to minimize plate prominence and soft tissue irritation.
- **Function:** The proposed OrthoPediatrics Wrist Fusion Plates provide stable fusion plating. This is similar to the predicate (K042355).
- **Sterilization:** The proposed OrthoPediatrics Wrist Fusion Plates are provided non-sterile and require sterilization prior to use which is the same sterilization method utilized for the predicate (K042355).

Summary of Performance Data (Nonclinical and/or Clinical)

- Non-Clinical Tests
  Non-clinical, four-point bend testing was performed comparing the proposed OrthoPediatrics Wrist Fusion Plates to the predicate Synthes LCP Wrist Fusion Plates (K042355). Testing concluded that the OrthoPediatrics Wrist Fusion Plates will perform equivalently to the Synthes LCP Wrist Fusion Plates. Based off the results of this testing, it is concluded that the proposed OrthoPediatrics Wrist Fusion Plates do not raise any new issues of safety and effectiveness and are substantially equivalent to the predicate Synthes LCP Wrist Fusion Plates (K042355).
- The proposed subject device system was evaluated in an MR environment and determined to be MR Conditional.
- Clinical Tests
  None provided as a basis for substantial equivalence.

Substantial Equivalence Conclusion

OrthoPediatrics believes that the Wrist Fusion Plates are substantially equivalent to the legally marketed predicate, Synthes LCP Wrist Fusion Plates (K042355) 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 OrthoPediatrics Wrist Fusion Plates will perform substantially equivalent to the legally marketed predicate device.