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

July 5, 2019

Re: K190324
Trade/Device Name: OrthoPediatrics Cannulated Screw System
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth Or Threaded Metallic Bone Fixation Fastener
Regulatory Class: Class II
Product Code: HWC
Dated: July 1, 2019
Received: July 3, 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,

For- Shumaya Ali, MPH
Assistant Director
DHT6C: Division of Stereotaxic, Trauma
and Restorative 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)*
K190324

Device Name
OrthoPediatrics Cannulated Screw System

Indications for Use *(Describe)*

Small Cannulated Screws (2.5mm – 4.0mm diameter)
Small Cannulated Screws (2.5mm - 4.0mm diameter) are intended for fixation of fractures and non-unions of small bones and small bone arthrodeses. Examples include, but are not limited to scaphoid and other carpal fractures, metacarpal and phalangeal fusions, osteotomies, and bunionectomies.

Large Cannulated Screws (4.5mm – 7.5mm diameter)
Large Cannulated Screws (4.5mm – 7.5 mm diameter) are intended for fracture fixation of large bones and large bone fragments. Diameters 6.5 mm and larger are intended for large bones and large bone fragments such as slipped capital femoral epiphyses; pediatric femoral neck fractures; tibial plateau fractures; SI joint disruptions; intercondylar femur fractures; subtalar arthrodesis and fixation of pelvis and iliosacral joint.

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 Cannulated Screw System 510(k) premarket notification. The submission was prepared in accordance with the FDA guidance document, 'The New 510(k) Paradigm – Alternate Approaches to Demonstration Substantial Equivalence in Premarket Notifications – Final Guidance', issued on March 20, 1998.

Sponsor: OrthoPediatrics, Corp.
2850 Frontier Drive
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Establishment Registration Number:
9102640 Phone: (574) 267-0880
Fax: (574) 269-3692

Contact: Jen Gregory
Regulatory Affairs Manager

Date: February 11, 2019

Subject Device: Trade Name: OrthoPediatrics Cannulated Screw System

Regulation Number: 888.3040

Regulation Name: Smooth or threaded metallic bone fixation fastener

Product Code: HWC

Common Name: Screw, Fixation, Bone

Legally marketed devices to which substantial equivalence is claimed:

Primary Predicate:

- K140891 – Biomet Cannulated Screw System

Secondary Predicates:

- K012945 – Synthes 2.4 mm Cannulated Screw – For the OrthoPediatrics 2.5-4.0 mm Cannulated Screws
- K963172 – Synthes 4.5 mm Cannulated Screw – For the OrthoPediatrics 4.5-7.5 mm Cannulated Screws

Device Description

The OrthoPediatrics Cannulated Screw System is a cancellous screw system intended for the use in the fixation of bone fragments. The subject Cannulated Screw System is composed of cannulated screws offered in a variety of sizes and options to accommodate patient anatomy, as well as washers and associated instrumentation to facilitate or aid in placement of the subject screws. The cannulated design of these screws allows them to be used in combination with a guide wire, also included in this

system, for precise placement into bone. The included Bone Screw Washers provide optional increased stabilization between the screw head and cortical bone. All subject screws and washers are manufactured from medical grade stainless steel per ASTM F138. All instruments are manufactured from stainless steel per ASTM F899, with the exception of the guide wires, which are manufactured from cobalt chrome per ASTM F562.

Intended Use and Indications for Use

Small Cannulated Screws (2.5mm – 4.0mm diameter)
Small Cannulated Screws (2.5mm - 4.0mm diameter) are intended for fixation of fractures and non-unions of small bones and small bone arthrodeses. Examples include, but are not limited to scaphoid and other carpal fractures, metacarpal and phalangeal fusions, osteotomies, and bunionectomies.

Large Cannulated Screws (4.5mm – 7.5mm diameter)
Large Cannulated Screws (4.5mm – 7.5 mm diameter) are intended for fracture fixation of large bones and large bone fragments. Diameters 6.5 mm and larger are intended for large bones and large bone fragments such as slipped capital femoral epiphyses; pediatric femoral neck fractures; tibial plateau fractures; SI joint disruptions; intercondylar femur fractures; subtalar arthrodesis and fixation of pelvis and iliosacral joint.

Summary of Technological Characteristics

The technological characteristics (materials, design, sizing) of the subject OrthoPediatrics Cannulated Screw System are similar to the following predicate devices:

Primary Predicate:

- K140891 – Biomet Cannulated Screw System

Secondary Predicates:

- K012945 – Synthes 2.4 mm Cannulated Screw – For the OrthoPediatrics 2.5-4.0 mm Cannulated Screws
- K963172 – Synthes 4.5 mm Cannulated Screw – For the OrthoPediatrics 4.5-7.5 mm Cannulated Screws

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

- **Intended Use:** The OrthoPediatrics Cannulated Screw System is intended for use in the fixation of small and large bone fragments, identical to the predicate devices.
- **Indications for Use:** Indications for Use are similar to the predicate Biomet Cannulated Screw System (K140891) and the predicate Synthes Cannulated Screws (K963172 and K012945).
- **Materials:** The proposed OrthoPediatrics Cannulated Screw System screws and washers are manufactured from 316L stainless steel conforming to ASTM F138 which is identical to the material of the predicate Synthes Cannulated Screws (K963172 and K012945)
- **Design Features:** The proposed OrthoPediatrics Cannulated Screw System incorporates similar design features and size ranges as the predicate devices.
- **Function:** The OrthoPediatrics Cannulated Screw System is intended for the use in the fixation of small and large bone fragments, identical to the predicate devices.

- **Sterilization:** The proposed OrthoPediatrics Cannulated Screw System is provided non-sterile and requires sterilization prior to use which is the same sterilization method utilized for the predicate devices, which are provided both sterile and non-sterile.

Performance Data

- Non-Clinical Tests
    - Torque to Failure per ASTM F543
    - Driving Torque per ASTM F543
    - Axial Pullout per ASTM F543

  Testing demonstrated the subject device to be substantially equivalent to predicate Synthes Cannulated Screws (K963172 and K012945) devices.
- The OrthoPediatrics Cannulated Screw System was evaluated for use in an MR Environment and were determined to be MR Conditional.
- Clinical Tests
  None provided as a basis for substantial equivalence.

Substantial Equivalence Conclusion

OrthoPediatrics believes that the subject device is substantially equivalent to the legally marketed predicate device based on intended use, technology, materials, as well as the mechanical testing and biocompatibility assessment.