DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

September 27, 2016

OrthoPediatrics, Corp.
Mr. Adam Cargill
Regulatory Affairs Associate Manager
2850 Frontier Drive
Warsaw, Indiana 46582

Re: K162307
Trade/Device Name: OrthoPediatrics Locking Proximal Femur System Cortical Screws
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories.
Regulatory Class: Class II
Product Code: HRS, HWC
Dated: September 1, 2016
Received: September 2, 2016

Dear Mr. 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 Parts 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Mark N. Melkerson -S

Mark N. Melkerson
Director
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)*

K162307

Device Name
OrthoPediatrics Locking Proximal Femur System Cortical Screws

Indications for Use *(Describe)*
The OrthoPediatrics Locking Proximal Femur System Cortical Screws are intended for temporary internal fixation and stabilization of long bone fractures and osteotomies, mal-unions, and non-unions, in pediatric and small stature adults. Specific indications include: intertrochanteric derotation and Varus osteotomies, femoral neck and pertrochanteric fractures, and intertrochanteric valgus osteotomies.

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 Locking Proximal Femur System Screws Special 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 Associate Manager

Date:
September 26, 2016

Subject Device:
Trade Name: OrthoPediatrics Locking Proximal Femur System Cortical Screws

Regulation Number: 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Product Code: HRS

Regulation Number: 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Product Code: HWC

Common Name(s): Plate, Fixation, Bone
Screw, Fixation, Bone

Legally marketed devices to which substantial equivalence is claimed:

- K111086 – OrthoPediatrics Locking Proximal Femur System

Device Description

The OrthoPediatrics Locking Proximal Femur System Cortical Screws are a line extension to expand the current offering to allow for longer cortical screws. The screws are part of one system that combines implants (plates and screws) and instruments. The additional cortical screw sizes include the following: 55mm, 60mm, 65mm, 70mm, 75mm, and 80mm.

- Materials: The cannulated screws are manufactured from medical grade BIODUR stainless steel which meet ASTM 2229-07 standard.
- Function: The system, which includes the cortical screws, functions to provide immediate stability and temporary fixation during the natural healing process.

Intended Use and Indications for Use

The OrthoPediatrics Locking Proximal Femur System Cortical Screws are intended for temporary internal fixation and stabilization of long bone fractures and osteotomies, mal-unions, and non-unions, in pediatric and small stature adults. Specific indications include: intertrochanteric derotation and Varus osteotomies, femoral neck and pertrochanteric fractures, and intertrochanteric valgus osteotomies.

Summary of Technological Characteristics

The technological characteristics (materials, design, sizing, and indications) of the Locking Proximal Femur System Cortical Screws are similar to the predicate system's screws.

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

Intended Use: The proposed Locking Proximal Femur System Cortical Screws are intended for temporary internal fixation and stabilization of long bone fractures and osteotomies, mal-unions, and non-unions, in pediatric and small stature adults which is the same as the predicate device.

Indications for Use: The proposed Locking Proximal Femur System Cortical Screws Indications for Use are identical to the predicate devices.

Materials: The proposed Locking Proximal Femur System Cortical Screws use the identical implant material as the predicate system's screws.

Design Features: The proposed Locking Proximal Femur System Cortical Screws incorporate similar design features as the predicate system's screws with the difference being the length of the screw and the change from cannulated to solid.

Sterilization: The proposed Locking Proximal Femur System Cortical Screws are provided non-sterile, which is identical to the predicate device.

Summary of Performance Data (Nonclinical and/or Clinical)

- Non-Clinical Tests
  - Engineering analysis was performed to show substantial equivalence between the subject device and predicate device.
- Clinical Tests - None provided as a basis for substantial equivalence.

Substantial Equivalence Conclusion

OrthoPediatrics believes that the Locking Proximal Femur System Cortical Screws are substantially equivalent to the legally marketed predicate system cortical screws (K111086) based on the similarities of design, intended use, materials, and the results of verification activities conducted. No new risks have been identified and it is expected that the Locking Proximal Femur System Cortical Screws will perform substantially equivalent to the legally marketed predicate device.