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

OrthoPediatrics, Corp.
Mr. Adam Cargill
Regulatory Affairs Associate Manager
2850 Frontier Drive
Warsaw, Indiana 46580

August 24, 2017

Re: K171173
Trade/Device Name: OrthoPediatrics Titanium PediPlates® System
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: June 23, 2017
Received: June 26, 2017

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 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.

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 (DICE) 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" (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.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education (DICE) 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
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)*
K171173

Device Name
OrthoPediatrics Titanium PediPlates® System

Indications for Use *(Describe)*
The OrthoPediatrics Titanium PediPlates® System is used for the express and sole purpose of redirecting the angle of growth of long bone(s). This is useful for gradually correcting angular deformities in growing children. Specific conditions/diseases for which the device will be indicated include: valgus, varus or flexion, extension deformities of the knee (femur and/or tibia), valgus, varus, or plantar flexion deformities of the ankle, valgus or varus deformities of the elbow (humerus), radial or ulnar deviation, flexion or extension deformities of the wrist (radius).

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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In accordance with 21 CFR §807.92 and the Safe Medical Devices Act of 1990, the following information is provided for the OrthoPediatrics' Titanium PediPlates® System 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: August 24, 2017

Subject Device: Trade Name: OrthoPediatrics Titanium PediPlates® System

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:

- K093442 – Orthofix Guided Growth System

Device Description

The OrthoPediatrics Titanium PediPlates® System consists of two and four-hole plates featuring a contoured mid-section and a low profile for pediatric use. There is a small provisional fixation hole in the center of the O and I-Plates to aid in accurate placement of the device relative to the growth plate. The plates are available in various sizes to accommodate variations in bone size and geometry. The plate is affixed to the bone using two to four screws (solid and cannulated), depending on which plate is selected.

- Materials: The plates and screws are manufactured from Ti-6Al-4V per ASTM F136.
- Function: The system functions to provide immediate stability and temporary fixation during the natural healing process.

Intended Use and Indications for Use

The OrthoPediatrics Titanium PediPlates® System is used for the express and sole purpose of redirecting the angle of growth of long bone(s). This is useful for gradually correcting angular deformities in growing children. Specific conditions/diseases for which the device will be indicated include: valgus, varus or flexion, extension deformities of the knee (femur and/or tibia), valgus, varus, or plantar flexion deformities of the ankle, valgus or varus deformities of the elbow (humerus), radial or ulnar deviation, flexion or extension deformities of the wrist (radius).

Summary of Technological Characteristics

The technological characteristics (materials, design, sizing, and indications) of the Titanium PediPlates® System are similar to the predicate Orthofix Guided Growth System (K093442).

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

Intended Use: The proposed Titanium PediPlates® System is used for the express and sole purpose of redirecting the angle of growth of long bones which is the same as the predicate K093442.
Indications for Use: Indications for Use are identical to the predicate.
Materials: The proposed Titanium PediPlates® System is manufactured from Ti-6Al-4V conforming to ASTM F136 which is the same material as the predicate.
Design Features: The proposed Titanium PediPlates® System incorporates similar design features as the predicate.
Sterilization: The proposed Titanium PediPlates® System is provided non-sterile and require sterilization prior to use which is the same sterilization method utilized for the predicate.

Summary of Performance Data (Nonclinical and/or Clinical)

- Non-Clinical Tests
  Non-clinical substantial equivalence testing including static bend testing, torsional testing, and four-point bend testing were performed comparing the proposed Titanium PediPlates® System to the Orthofix Guided Growth System (K093442). Testing concluded that the Titanium PediPlates® System will performed equivalently to the Orthofix Guide Growth System.
- The proposed Titanium PediPlates® System was tested 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 Titanium PediPlates® System is substantially equivalent to the legally marketed predicate, Orthofix Guide Growth Plate System (K093442) 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 Titanium PediPlates® System will perform substantially equivalent to the legally marketed predicate device.