January 18, 2022

Orthofix Srl
℅ Cheryl Wagoner
Consultant
Wagoner Consulting LLG
PO Box 15729
Wilmington, North Carolina 28408

Re: K213572
Trade/Device Name: JuniOrtho Plating System™
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth Or Threaded Metallic Bone Fixation Fastener
Regulatory Class: Class II
Product Code: HWC
Dated: November 8, 2021
Received: November 10, 2021

Dear Cheryl Wagoner:

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,

Shumaya Ali, MPH
Assistant Director
DHT6C: Division of Restorative, Repair
and Trauma 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

K213572

Device Name
JuniOrtho Plating System™

Indications for Use *(Describe)*

The JPS JuniOrtho Plating System™ is intended for internal fixation and stabilization of fractures, osteotomies, mal-unions and non-unions of long bones of the lower limb.
The JPS JuniOrtho Plating System™ is indicated for internal fixation and stabilization of femoral and tibial fractures, osteotomies, mal-unions and non-unions.
Indications include:
- Varus, valgus, rotational and/or shortening osteotomies
- Femoral neck and/or pertrochanteric fractures
- Proximal and distal metaphyseal fractures
- Pathological and impeding pathological fractures

Use of the JPS JuniOrtho Plating System™ is indicated in pediatric (excluding newborns) and small stature adult patients.

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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ORTHOFIX

510(k) Summary for K213572

(21 CFR 807.92)

Submitter information

Submitter Name	Orthofix Srl
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Email address	GianlucaRicadona@orthofix.it
Date of summary	January 18, 2022

Trade Name, Common Name, Classification

Trade Name	JPS JuniOrtho Plating System™
Device	Screw, fixation, bone
Product code	HWC
Panel Code	Orthopedic
Class	Class II
Classification Regulation Number	21 CFR 888.3040

Predicate devices

Primary Predicate Device	**510(k) Number**	**Manufacturer**
JPS JuniOrtho Plating System™	K200246	Orthofix Srl
Other Predicate Devices		
Synthes Lcp Pediatric Plates	K112085	Synthes (USA) Products LLC

Orthopediatrics Pediloc™ Tibial Plate System	K100240	Orthopediatrics, Corp.

Device description	The Subject Device is a line extension of the existing locking and non-locking screws with same indications and intended use, diameters and new lengths, and with a modified geometry, to be used in addition to those already cleared for use (JPS JuniOrtho Plating System K200246). The predicate device, screws are offered both in sterile and non-sterile packaging configurations and are made from Stainless steel AISI 316LVM, according to ASTM F138 “Standard Specification for Wrought 18Chromium-14Nickel-2.5Molybdenum Stainless Steel Bar and Wire for Surgical Implants (UNS S31673)”.
Indications for use	Being a Line Extension, the Indications for use of the Subject device are identical to the predicate’s JPS JuniOrtho Plating System™ and are referred to the whole system as follows. JPS JuniOrtho Plating System™ is intended for internal fixation and stabilization of fractures, osteotomies, mal-unions and non-unions of long bones of the lower limb. The JPS JuniOrtho Plating System™ is indicated for internal fixation and stabilization of femoral and tibial fractures, osteotomies, mal-unions and non-unions. Indications include: - Varus, valgus, rotational and/or shortening osteotomies - Femoral neck and/or pertrochanteric fractures - Proximal and distal metaphyseal fractures - Pathological and impeding pathological fractures Use of the JPS JuniOrtho Plating System™ is indicated in pediatric (excluding newborns) and small stature adult patients.
Technological Characteristics and Intended Use	Documentation was provided to demonstrate that the Subject device is substantially equivalent to the predicate JPS JuniOrtho Plating System (K200246) component(s), in the following fundamental aspects: Intended use, indications for use, intended population, sites of application, operating principles and method of fixation, material, conditions of use, mechanical performances, basic design, packaging configuration, sterilization method, biocompatibility and MRI compatibility.

Performance Data	The design dimensional specification change of the Subject device has been managed by design control activity and Risk Management process. The potential identified risks have been measured and mitigated through mechanical testing, in order to demonstrate that the Subject Device does not introduce additional risks respect to the predicate (K200246). The testing activity results demonstrated to meet the established acceptance criteria. The following standards have been followed to perform mechanical test on the Subject device: ASTM F543 – 17 “Standard Specification and Test Methods for Metallic Medical Bone Screws”.
Biocompatibility data	The Subject device is equivalent in its final finished formof the predicate device, JPS JuniOrtho Plating System (K200246), concerning the: manufacturing, sterilization, processing, material, intended population, anatomical location and duration of exposure. Therefore, no additional biocompatibility assessment was required for the Subject device.
Conclusion	The analysis on the performance data within this Premarket Notification supports the conclusion that the new Subject device is substantially equivalent to the predicate (K200246).