May 22, 2020

Orthofix Srl
℅ Cheryl Wagoner
Consultant
Wagoner Consulting LLC
PO Box 15729
Wilmington, North Carolina 24408

Re: K200246
Trade/Device Name: JPS JuniOrtho Plating 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: January 31, 2020
Received: January 31, 2020

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K200246

Device Name

JPS 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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510(k) Summary
(21 CFR 807.92)

Submitter information

Submitter Name	Orthofix Srl
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Email address	GianlucaRicadona@orthofix.it
Date of submission	May 22, 2020

Trade Name, Common Name, Classification

Trade Name	JPS JuniOrtho Plating System™
Common name	Plating system
Device	Plate, fixation, bone Screw, fixation, bone
Product code	HRS HWC
Panel Code	Orthopedic
Classification	Class II
Regulation Number	21 CFR 888.3030 21 CFR 888.3040

Predicate devices and reference devices

Predicate Device	**510(k) Number**	**Manufacturer**
Primary Predicate		
Synthes Lcp Pediatric Plates	K112085	Synthes (Usa) Products LLC
Additional Predicate		
Orthopediatrics Pediloc™ Tibial Plate System	K100240	Orthopediatrics, Corp.
Reference Device		
Orthopediatrics Pediloc™ Locking Plate System	K083286	Orthopediatrics, Corp.
Orthofix External Fixation Screw (Pin) With Hydroxyapatite Coating	K974186	Orthofix Srl
Orthofix Titanium Nailing Systems	K053261	Orthofix Srl

Device description	The JPS JuniOrtho Plating System™ consists of plate's sizes and shapes ranges, designed to accept locking and cortical bone screws, which are available in a variety of diameters and lengths, in order to support internal fixation and stabilization of fractures, osteotomies, mal-unions and non-unions in long bones of lower limbs. The JPS JuniOrtho Plating System™ is designed according to the anatomic region of clinical application: femur and tibia. The implants would be offered both in sterile and non-sterile packaging configurations.

	The subject device implants, bone plates and bone screws, 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)*". Surgical procedures with the use of the subject implants may be performed with the support of general orthopedic instrumentation, to facilitate their proper insertion and removal from the patient. The instruments and accessories offered by Orthofix are classified as class I devices exempt from 510(k), under the product code LXH, according to *21 CFR 888.4540* Orthopedic Manual Surgical Instrument, and product code FSM according to 21 CFR 878.4800 Manual surgical instrument for general use. These instruments are made by medical grade stainless steel (AISI 316LVM, AISI 630, AISI 420B, AISI 303, X15TN), Aluminum alloy (EN-AW 6082 T6), and plastic material (PP-H PROPILUX). JPS JuniOrtho Plating System™ is designed to be used in the operating theatre only.
Indications for use	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.
Technological Characteristics and Intended Use	The subject device fundamental scientific principles and technological characteristic, including: the intended use, material and general design, are the same as, or similar to, the chosen predicate devices. Summary of the technological characteristics and Intended Use: ✓ *Intended use*: identical. ✓ *Indications for Use, Anatomical sites, operating principles and conditions of use*: are substantially equivalent to predicates; no new risks associated to the subject device with combined indications for use compared to those of the predicates which have definite indications for use for anatomical site, having demonstrated substantially equivalent safety and effectiveness to the anatomical sites specific for each predicate device. ✓ *Material* are equivalent (Stainless Steel); ✓ *Geometry and size*: similar sizes and geometry of the bone plates; similar sizes and geometry of the bone screws. ✓ *Sterilization*, same method as the two predicates. The *technological characteristics* of the JPS JuniOrtho Plating System™ are substantially equivalent to the predicate devices.

Performance Analysis	Subject device has similar configuration, material, sizes and design as the predicate devices. Bench testing and engineering assessments on worst cases of subject device and corresponding predicate devices, confirm that subject devices have equivalent or better mechanical performances. Testing was done per consensus standards: ASTM F382-17, F384-17, F543-17, and F1264-16. Any potential hazards have been evaluated and controlled through Risk Management activities. The review of clinical literatures on similar devices still support the clinical data of the Subject devices with no additional clinical information.
Conclusion	Based upon equivalences in: intended use, site of application, conditions of use, operating principles, and the non-clinical performance data, the JPS JuniOrtho Plating System™ has been shown to be safe and effective, and performs as well as or better than the legally marketed predicate devices. Therefore, the Subject device is expected to be declared substantially equivalent to the legally marketed predicate devices.