April 20, 2021

Orthofix SRL
% Cheryl Wagoner
Consultant
Wagoner Consulting LLC
PO Box 15729
Wilmington, North Carolina 28408

Re: K210157
Trade/Device Name: SOLE™ Medial Column Fusion Plate
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 21, 2021
Received: January 21, 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)*

K210157

Device Name
SOLE™ Medial Column Fusion Plate

Indications for Use *(Describe)*

The SOLE™ Medial Column Fusion Plate is intended to provide bone fixation.
The SOLE™ Medial Column Fusion Plate is indicated for orthopedic applications within the anatomical area of the foot and ankle, including but not limited to the medial column (consisting of the first metatarsal, medial cuneiform, navicular and talus). Specific indicated procedures include:
- Arthrodesis;
- Joint depression stabilization;
- Fracture and/or osteotomy fixation;
- Reconstruction;
- Revision

to be performed for conditions such as Charcot neuroarthropathy.

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	April 16, 2021

Trade Name, Common Name, Classification

Trade Name	SOLE™ Medial Column Fusion Plate
Device	Plate, fixation, bone (Primary) Screw, fixation, bone
Product code	HRS (Primary) HWC
Panel Code	Orthopedic
Class	Class II
Regulation Number	21 CFR §888.3030 (Primary): Single/multiple component metallic bone fixation appliances and accessories; 21 CFR §888.3040: Smooth or threaded metallic bone fixation fastener; Class II.

Predicate devices and reference devices

Primary Predicate Device	**510(k) Number**	**Manufacturer**
Baby Gorilla/Gorilla Plating System (formerly ParaLock Plating System™)	K203511	Paragon 28, Inc.
Additional Predicate Devices		
VariAx 2 System	K180500	Stryker GmbH
VLP Foot, Plating, Screw System	K090675	Smith & Nephew, Inc
Salvation 3Di Plating System	K140792	Wright Medical
Reference Devices		
Orthofix Fixation Screws with HA coated	K974186	Orthofix Srl
Veronail Screwdriver instrument	K053261	Orthofix Srl
Chimaera - Hip Fracture System	K173458	Orthofix Srl

Device description	The SOLE™ Medial Column Fusion Plate consists of plate's sizes and shapes ranges, designed to accept locking and non-locking bone screws, which are available in a variety of diameters and lengths, in order to address demands of stabilization, fixation and fusion of small bones and small joints within the anatomical area of the foot and ankle.

	The implants will be offered both in sterile and non-sterile packaging configurations. Plates and screws are intended for single use only. Screws are not intended for use in the spine. The Subject device implants, bone plates and bone screws, are made from Stainless Steel AISI 316 LVM according to Standard ISO 5832-1/ASTM F138. 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 offered by Orthofix are classified as class I devices Exempt from 510(k), under the product code LXH, according to 21CFR 888.4540 Orthopedic Manual surgical instrument. These instruments are made by medical grade stainless steel (AISI 316LVM, AISI 630, AISI 301, AISI 303, X15TN) and Aluminum alloy (EN-AW 6082 T6). SOLE™ Medial Column Fusion Plate is designed to be used in the operating theatre only.
Indications for use	The SOLE™ Medial Column Fusion Plate is intended to provide bone fixation. The SOLE™ Medial Column Fusion Plate is indicated for orthopedic applications within the anatomical area of the foot and ankle, including but not limited to the medial column (consisting of the first metatarsal, medial cuneiform, navicular and talus). Specific indicated procedures include: - Arthrodesis; - Joint depression stabilization; - Fracture and/or osteotomy fixation; - Reconstruction; - Revision to be performed for conditions such as Charcot neuroarthropathy.
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 compared to those of the Primary predicate and the additional predicate device which have equivalent indications for use, anatomical sites and conditions of use. Verification activities on Subject devices demonstrated substantially equivalent performance to the predicate devices. ✓ *Geometry and size*: similar sizes and geometry of the bone plates; similar sizes and geometry of the bone screws. ✓ *Sterilization*, same method as the predicates.

	The *technological characteristics* of the SOLE™ Medial Column Fusion Plate are substantially equivalent to the predicate devices.
Performance Analysis	Subject device has similar configuration, sizes and design as the predicate devices. Results to support the determination of substantial equivalence from bench testing and engineering assessments on worst cases of Subject device and corresponding predicate devices and other similar devices, confirm that Subject device, as safe, as effective, and performs as well as or better than the predicate devices. Performance mechanical testing on Subject implants item have been performed according to: ASTM F543-17 “Standard Specification and Test Methods for Metallic Medical Bone Screws”, ASTM F382 standard “Standard Specification And Test Method For Metallic Bone Plates”, ASTM F543-17 “Standard Specification and Test Methods for Metallic Medical Bone Screws”. Performance mechanical testing specifications on Subject instruments according to standard ASTM F899-12b “Standard Specification for Wrought Stainless Steels for Surgical Instruments”. Any potential hazards have been evaluated and controlled through Risk Management activities, and any relevant information, have been addressed in the labelling, after all control measures have been implemented. The review of the current clinical literature on the predicates and on other similar devices have been conducted to support the clinical indications of SOLE™ Medial Column Fusion Plate without requiring further clinical data.
Conclusion	Based upon equivalences in: intended use, site of application, conditions of use, operating principles, and the non-clinical performance data, the SOLE™ Medial Column Fusion Plate has been shown to be safe and effective, and to perform equivalently as compared to the legally marketed predicate devices. Therefore, the Subject device is substantially equivalent to the legally marketed predicate devices.