June 7, 2019

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

Re: K190388
Trade/Device Name: RIVAL View Plating Systems and Reduce Fracture Plating Systems
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: February 8, 2019
Received: February 19, 2019

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)*
K190388

Device Name
RIVAL™ View Plating System™ and Reduce Fracture Plating System™

Indications for Use *(Describe)*
RIVAL™ View Plating System™ and Reduce Fracture Plating System™ are intended for use in stabilization and fixation of fresh fractures, revision procedures, joint fusion, and reconstruction of small bones of the hand, feet, wrist, ankles, fingers and toes. The plates are available for use with Rival locking and non-locking bone screws.

Plates and screws are intended for single use only. Screws are not intended for use in the spine.

Examples of these procedures for which the RIVAL™ View Plating Systems™ may be used, but are not limited to:

- First metatarsal osteotomies for hallux valgus correction including:
  - Opening base wedge osteotomy
  - Closing base wedge osteotomy
  - Crescentic osteotomy
  - Proximal Chevron osteotomy
  - Distal Chevron osteotomy (Austin)

- First metatarsal fracture fixation

- Arthrodesis of the first metatarsalcuneiform joint (Lapidus Fusion)

- Arthrodesis of the first metatarsophalangeal joint (MTP) including:
  - Primary MTP Fusion due to hallux rigidus and/or hallux valgus
  - Revision MTP Fusion
  - Revision of failed first MTP Arthroplasty Implant

- Calcaneal-Cuboid Fusion

- Talonavicular Fusion

- Evans Osteotomy

Example of indications for which the RIVAL™ Reduce Plating Systems™ may be used, but are not limited to:
- Metatarsal or metacarpal fractures and osteotomies
- Phalanges fractures and osteotomies
- Lapidus Fusion
- Lisfranc Arthrodesis
- 1st MPJ Arthrodesis
- Forefoot 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)

510(k) Summary

A 510(k) Summary of the safety and effectiveness information upon which this substantial equivalence determination is based, is provided in this section.

510(k) Summary

(21 CFR 807.92)

Submitter information

Submitter Name	Orthofix Srl
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Date Prepared	June 7, 2019

Trade Name, Common Name, Classification

Trade Name	RIVAL™ View Plating System™ and Reduce Fracture Plating System™
Common Name	Plating System
Panel Code	Orthopedic
Class	Class II
Classification Name and Product code	Plate, Fixation, Bone (21 CFR 888.3030, Product Code HRS) Screw, Fixation, Bone (21 CFR 888.3040, Product Code HWC)

Predicate device

Predicate Device	**510(k) Number**	**Manufacturer**
Primary Predicate		
EDGE Orthopaedics VIEW and REDUCE Plating Systems	K140876	ORTHOFIX SRL
Reference device		
Orthopaedics REDUCE Fracture Plating System Line Extension	K142135	ORTHOFIX SRL

Device description	RIVAL™ View Plating System™ and Reduce Fracture Plating System™ has been designed to support multiple indications within the forefoot and mid-foot. The Subject device introduces new line extension codes, in sterile and non-sterile configuration. Subject device is manufactured by the same material (Ti6Al4V) and by the same manufacturer Orthofix Srl as the predicate EDGE Orthopaedics VIEW and REDUCE Plating System.

Indications for use	As the predicate EDGE Orthopaedics VIEW and REDUCE Plating System, the Subject device are intended for use in stabilization and fixation of fresh fractures, revision procedures, joint fusion, and reconstruction of small bones of the hand, feet, wrist, ankles, fingers and toes. The plates are available for use with Orthofix locking and non-locking bone screws. Plates and screws are intended for single use only. Screws are not intended for use in the spine. Examples of these procedures for which the Rival View Plating System may be used, but are not limited to: • First metatarsal osteotomies for hallux valgus correction including: - Opening base wedge osteotomy -Closing base wedge osteotomy - Crescentic osteotomy - Proximal Chevron osteotomy - Distal Chevron osteotomy (Austin) • First metatarsal fracture fixation • Arthrodesis of the first metatarsal-cuneiform joint (Lapidus Fusion) • Arthrodesis of the first metatarsophalangeal joint (MTP) including: - Primary MTP Fusion due to hallux ridgidus and/or hallux valgus - Revision MTP Fusion - Revision of failed first MTP Arthroplasty Implant • Calcaneal-Cuboid Fusion • Talonavicular Fusion • Evans Osteotomy Example of indications for which the Rival Reduce Fracture Plating System may be used, but are not limited to: • Metatarsal or metacarpal fractures and osteotomies • Phalanges fractures and osteotomies • Lapidus Fusion • Lisfranc Arthrodesis • 1st MPJ Arthrodesis • Forefoot osteotomies
Technological Characteristics and Intended Use	The fundamental scientific principles and technological characteristic, including the intended use, material and general design are the same as, or similar to, the predicate devices. Summary of the technological characteristics: ✓ Plate thickness, geometry and width(s) are identical to the predicates. ✓ Range of plate angles are identical to predicates. ✓ Identical material (Titanium Alloy) to the cited predicates ✓ Locking and non-locking screws same as the predicates, ✓ Sterile method, same as the predicates ✓ Indications for Use and anatomical site, , operating principles, conditions of use are substantially equivalent to predicates. The technological characteristics of the subject device and the predicates are substantially equivalent to the predicates.

Performance Analysis	Subject device has similar configuration, material, sizes and design as the predicate devices. Mechanical performance and engineering assessment with worst case of subject device and corresponding predicate devices, confirm that subject devices have equivalent or better strength and resistance. Any potential hazard 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. Pyrogenicity testing was conducted in support of substantial equivalence.
Conclusion	Based upon equivalences in: intended use, site of application, , conditions of use, performance data, operating principles, and according to the results of nonclinical testing, the subject devices belonging to RIVAL™ VIEW Plating System™ and REDUCE Fracture Plating System™ have been shown to be safe, as effective, and performs as well as or better than the legally marketed predicate device. Therefore, the Subject device is expected to be substantially equivalent to the legally marketed predicate devices.