February 7, 2018

Orthofix Srl
Gianluca Ricadona
Sr. Quality & Regulatory Affairs Manager
Via delle Nazioni, 9
37012 Bussolengo (VR)
Italy

Re: K172698
Trade/Device Name: G-Beam Fusion Beaming System
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth Or Threaded Metallic Bone Fixation Fastener
Regulatory Class: Class II
Product Code: HWC
Dated: January 5, 2018
Received: January 8, 2018

Dear Gianluca Ricadona:

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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Katherine D. Kavlock -S

for
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K172698

Device Name
G-Beam™ Fusion Beaming System

Indications for Use *(Describe)*
The G-Beam™ Fusion Beaming System is intended to be inserted in the bones of the foot and ankle for alignment, stabilization and fixation of various fractures and osteotomies, fusions and reconstructions.
It is indicated for fracture and osteotomy fixation, reconstruction procedures, non-unions and fusions of bones of the foot and ankle including metatarsals, cuneiforms, cuboid, navicular, calcaneus and talus.
Specific example: medial and lateral column fusions resulting from neuropathic osteoarthropathy (Charcot osteoarthropathy).

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

(as required by 21 CFR 807.92)

Submitter Name	Orthofix Srl
Address	Via delle Nazioni, 9 | 37012 Bussolengo (VR) - Italy
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Contact Person	Gianluca Ricadona Sr. Quality & Regulatory Affairs Manager
Address	Via delle Nazioni, 9 37012 Bussolengo (VR) - Italy
Telephone	+ 39 045 6719 000
Fax	+ 39 045 6719 380
email	GianlucaRicadona@orthofix.it
Date Prepared	February 5, 2018

Trade Name	G-Beam™ Fusion Beaming System
Common Name	Screw, fixation, bone
Panel Code	Orthopedic
Classification Name	Smooth or threaded metallic bone fixation fastener
Class	Class II
Regulation Number	21 CFR 888.3040
Product Code	HWC

Predicate Device Name	**510(k) Number**	**Manufacturer**
SALVATION™ Beams and Bolts System	K140741	Wright Medical Technology, Inc.
Axis Charcot Fixation System	K171018	Extremity Medical LLC
Orthofix External Fixation Screw (Pin) with hydroxyapatite coating (Reference device)	K974186	Orthofix SRL
Orthofix Titanium Nailing Systems (Reference device)	K053261	Orthofix SRL

Device description	The G-Beam™ Fusion Beaming System has been designed to address the specific demands of advanced deformity and trauma reconstructions of foot and ankle applications. The system was developed for the treatment of neuropathic deformities, such as Charcot, requiring fusion of the medial and/or lateral columns, with or without corrective osteotomies as well as for joint fusions within the mid- and hindfoot. The G-Beam™ Fusion Beaming System consists of two different diameter implant ranges, designed for optimal implant selection for wide ranging patient anatomies and an instrumentation including the dedicated G-Beam Sterilization Tray. The G-Beam™ Fusion Beaming System is designed with an instrumentation and technique that have been developed to simplify the surgery.
Indications for use	The G-Beam™ Fusion Beaming System is intended to be inserted in the bones of the foot and ankle for alignment, stabilization and fixation of various fractures and osteotomies, fusions and reconstructions. It is indicated for fracture and osteotomy fixation, reconstruction

	procedures, non-unions and fusions of bones of the foot and ankle including metatarsals, cuneiforms, cuboid, navicular, calcaneus and talus. Specific example: medial and lateral column fusions resulting from neuropathic osteoarthropathy (Charcot osteoarthropathy).

Technological Characteristics and Substantial Equivalence	Documentation was provided to demonstrate that the G-Beam™ Fusion Beaming System is substantially equivalent to the legally marketed predicates. Components and instrumentation included in the G-Beam™ Fusion Beaming System and the predicate device are both internal fracture fixation systems, as defined in 21 CFR 888.3040. The G-Beam™ Fusion Beaming System is substantially equivalent to the predicate devices in: intended use, site of application, patient population, conditions of use, mechanical performances, operating principles. Mechanical testing show how the mechanical properties of the subject device are equivalent or better than the predicate device.
Performance Data	The potential hazards have been evaluated and controlled through a Risk Management Plan. All testing met or exceeded the requirements as established by the test protocols and applicable standards. A review of the mechanical data indicates that the components of the Subject device are capable of withstanding expected loads without failure. The Subject device was therefore found to be substantially equivalent to the predicate device. Clinical data was not needed to support the safety and effectiveness of the Subject Device. Mechanical testing was performed according to the following standards: • ASTM F1264-16 “Standard Specification and Test Methods for Intramedullary Fixation Devices”. • ASTM F-543-13 “Standard Specification and Test Methods for metallic bone screws”
Pyrogenicity data	In order to establish the Subject device non-pyrogenicity, tests were performed according to the following international standards: • USP 38: 2014 < 85 > “Bacterial endotoxin test (LAL)”. • USP 38: 2014 < 161 > “Medical devices – bacterial endotoxin and pyrogen tests”. • ANSI / AAMI ST72: 2011 “Bacterial endotoxins – Test methodologies, routine monitoring and alternative batch testing”.
Conclusion	Based upon similarities in: intended use, site of application, patient population, conditions of use, mechanical performances, operating principles, and according to the results of mechanical testing, G-Beam™ Fusion Beaming System has been shown to be substantially equivalent to the legally marketed predicate device and to be as safe and effective as the predicate for its intended use.