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

December 7, 2017

Re: K173458
Trade/Device Name: ORTHOFIX CHIMAERA Hip Fracture System - Trochanteric Nailing System
Regulation Number: 21 CFR 888.3020
Regulation Name: Intramedullary Fixation Rod
Regulatory Class: Class II
Product Code: HSB
Dated: November 6, 2017
Received: November 7, 2017

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. 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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K173458

Device Name
ORTHOFIX CHIMAERA Hip Fracture System - Trochanteric Nailing System

Indications for Use *(Describe)*
The ORTHOFIX CHIMAERA Hip Fracture System – trochanteric nailing system is intended for insertion into the medullary canal of a femur for the alignment, stabilization and fixation of various types of fractures or deformities.

The ORTHOFIX CHIMAERA Hip Fracture System - trochanteric nailing system is indicated for treatment of stable and unstable pertrochanteric, intertrochanteric and subtrochanteric fractures of the femur alone or when these fractures occur in combination with shaft fractures extending distally to a point approximately 10 cm proximal to the intercondylar notch. These includes traumatic fractures, refractures, non-union, reconstruction, malunion, malalignment, pathological fractures and impending pathological fractures.

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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Special 510(k) Premarket Notification
ORTHOFIX CHIMAERA Hip Fracture System - Trochanteric Nailing System

510(k) Summary
(as required by 21 CFR 807.92)

Submitter	Orthofix Srl	
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email	GianlucaRicadona@orthofix.it	
Submission date	11/06/2017	
Trade Name	ORTHOFIX CHIMAERA Hip Fracture System - Trochanteric Nailing System	
Common Name	Rod, fixation, intramedullary and accessories	
Panel Code	87 / Orthopaedic	
Classification Name	Intramedullary fixation rod.	
Class	Class II	
Regulation Number	21 CFR 888.3020	
Product Code	HSB	
Name of Predicate Device	**510(k) #**	**Manufacturer**
ORTHOFIX CHIMAERA Hip Fracture System - Trochanteric Nailing System	K161466	Orthofix Srl
Description	The ORTHOFIX CHIMAERA Hip Fracture System – Trochanteric Nailing System consists of implantable components (nails, end caps and screws) and instrumentation. The proximal part of the nail features a threaded bore to connect the nail to the targeting handle by means of a cannulated bolt. The insertion of the nail into the femur medullary canal is typically performed by some instruments, including: guide wire, awl, reamer and impactor elements.	
Intended Use **Indications for use**	The ORTHOFIX CHIMAERA Hip Fracture System – Trochanteric Nailing System is intended for insertion into the medullary canal of a femur for the alignment, stabilization and fixation of various types of fractures or deformities. The ORTHOFIX CHIMAERA Hip Fracture System – Trochanteric Nailing System is indicated for treatment of stable and unstable pertrochanteric, intertrochanteric and subtrochanteric fractures of the femur alone or when these fractures occur in combination with shaft fractures, or when these fractures occur in combination with shaft fractures extending distally to a point approximately 10 cm proximal to the intercondylar notch.	

	These includes traumatic fractures, re-fractures, non-union, reconstruction, malunion, malalignment, pathological fractures and impending pathological fractures.
Technological Characteristics and Substantial Equivalence	Documentation provided demonstrates that the ORTHOFIX CHIMAERA Hip Fracture System – Trochanteric Nailing System is substantially equivalent to the legally marketed predicate. The components and instruments included in the Subject System and the predicate are all internal fracture fixation systems, as defined in 21 CFR 888.3020. The ORTHOFIX CHIMAERA Hip Fracture System – Trochanteric Nailing System is substantially equivalent to the predicate device in: intended use and Indications for use, site of application, patient population, condition of use, basic design, technology, materials, implantable components and mechanical performances.
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 standard. A review of the mechanical data indicates that the components of the Subject device continues to be capable of withstanding expected loads without failure. The Subject device was therefore found to be substantially equivalent to the Predicate device and has the mechanical properties to perform its indications safely. Clinical data was not needed to support the safety and effectiveness of the Subject Device. The following standard has been followed to perform mechanical test on the System configuration: • ASTM F1264 -16 Standard Specifications and Test Methods for Intramedullary Fixation Devices.
Conclusion	Based upon similarities in: intended use and Indications for use, site of application, patient population, condition of use, basic design, technology, materials, implantable components and mechanical performances, the Subject System has been shown to be substantially equivalent to the legally marketed predicate device and to be safe and effective for its intended use.