DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

January 24, 2017

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

Re: K161466
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: December 23, 2016
Received: December 27, 2016

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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson -S

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)*
K161466

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, re-fractures, 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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Attachment 7

510(k) Summary
K161466
(as required by 21 CFR 807.92)

Submitter Name	Orthofix Srl
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email	GianlucaRicadona@orthofix.it
Date Prepared	May 26, 2016

Trade Name	ORTHOFIX CHIMAERA Hip Fracture System – Trochanteric Nailing System
Common Name	Rod, fixation, intramedullary and accessories
Panel Code	Orthopedic
Classification Name	Intramedullary fixation rod.
Class	Class II
Regulation Number	21 CFR 888.3020
Product Code	HSB

Primary Predicate	Predicate Device Name	510(k)	Manufacturer
√	Orthofix Titanium Nailing System (VeroNail)	K053261	Orthofix Srl
	Gamma3 Nail System	K043431	Howmedica Osteonics Corp.

Device 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 and Indications	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 was provided to demonstrate that the ORTHOFIX CHIMAERA Hip Fracture System – Trochanteric Nailing System is substantially equivalent to the legally marketed predicates. Components and instrumentation included in the ORTHOFIX CHIMAERA Hip Fracture System – Trochanteric Nailing System and the predicate devices 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 devices in: intended use, site of application, patient population, conditions of use, mechanical performances, operating principles and materials. The ORTHOFIX CHIMAERA Hip Fracture System – Trochanteric Nailing System is comparable to its predicate in dimensions and materials. Mechanical testing show how the mechanical properties of the subject device are equivalent or better than the predicate devices.
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 devices. Clinical data was not needed to support the safety and effectiveness of the Subject Device. Mechanical testing was performed according to the following standards: • ISO 7206-4 “Implants for surgery - Partial and total hip joint prostheses - Part 4: Determination of endurance properties and performance of stemmed femoral components”. • ISO 12107 “Metallic materials - Fatigue testing - Statistical planning and analysis of data”. • ASTM F384-12 “Standard Specifications and Test Methods for Metallic Angled Orthopedic Fracture Fixation Devices”. • ASTM F1264-14 “Standard Specification and Test Methods for Intramedullary Fixation Devices”.
Biocompatibility data	In order to establish non-pyrogenicity of the Subject device, additional tests were performed according to the following international standard: • 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". • FDA 2012 Q&A "Guidance for Industry Pyrogen and Endotoxins Testing: Question and Answers". Here below the tests references list: • Validation report 16VA00533 • Test report Cert_2016_7505 • Test report Cert_2016_7506 • Test report Cert_2016_7507.
Conclusion	Based upon similarities in: intended use, site of application, patient population, conditions of use, mechanical performances, operating principles, materials and for the results of mechanical testing, ORTHOFIX CHIMAERA Hip Fracture System – Trochanteric Nailing System has been shown to be substantially equivalent to the legally marketed predicate devices.