Orthofix Srl
% Chery Wagoner
Consultant
Wagoner Consulting LLC
PO Box 15729
Wilmington, North Carolina 24408

November 16, 2017

Re: K173051
Trade/Device Name: Orthofix MJ-FLEX THE NEW METAIZEAU NAIL
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth Or Threaded Metallic Bone Fixation Fastener
Regulatory Class: Class II
Product Code: HTY
Dated: September 8, 2017
Received: September 28, 2017

Dear Chery 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,

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K173051

Device Name
Orthofix MJ-Flex The New Metazeau Nail

Indications for Use *(Describe)*
The MJ-FLEX THE NEW METAIZEAU NAIL™ is intended for the treatment of diaphyseal fractures of long bones.

The MJ-FLEX THE NEW METAIZEAU NAIL™ is indicated to treat:
- upper extremity and clavicle fractures in all patients except newborns and infants;
- lower extremity fractures in pediatric patients, except newborns and infants, where the flexibility of the implant is paramount not to disrupt the growth plate;
- lower extremity fractures in small adults where the medullary canal is narrow.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

ORTHOFIX®

510(k) Summary

(as required by 21 CFR 807.92)

Submitter	Orthofix Srl
	Via delle Nazioni, 9 | 37012 Bussolengo (VR) - Italy
Telephone	+ 39 045 6719.000
Fax	+ 39 045 6719.380

Contact Person	Gianluca Ricadona Sr. Quality and 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.com
Date Prepared	September 8th, 2017

Trade Name	Orthofix MJ-FLEX THE NEW METAIZEAU NAIL™
Common Name	Pin, fixation, smooth
Panel Code	Orthopaedics/87
Classification Name	Smooth or threaded metallic bone fastener
Class	Class II
Regulation Number	21 CFR 888.3040
Product Code	HTY

Predicate Device Name	**510(k) Number**	**Manufacturer**
OrthoPediatrics PediFlex™ Flexible Nail System	K082375	Orthopediatrics

Description	The Orthofix MJ-FLEX THE NEW METAIZEAU NAIL™ is an intramedullary implant system specifically designed for Elastic Stable Intramedullary Nailing (ESIN) fracture fixation. The System consists of implantable components (intramedullary nails) and instrumentation. Nails are supplied in different diameters and lengths, in order to assure compatibility with patient anatomy, and in both Titanium alloy and Stainless Steel materials.

Indications for Use	The MJ-FLEX THE NEW METAIZEAU NAIL™ is intended for the treatment of diaphyseal fractures of long bones. The MJ-FLEX THE NEW METAIZEAU NAIL™ is indicated to treat: - upper extremity and clavicle fractures in all patients except newborns and infants;

	- lower extremity fractures in pediatric patients, except newborns and infants, where the flexibility of the implant is paramount not to disrupt the growth plate; - lower extremity fractures in small adults where the medullary canal is narrow.

Technological Characteristics and Substantial Equivalence	Documentation was provided to demonstrate that the Orthofix MJ-FLEX THE NEW METAIZEAU NAIL™ is substantially equivalent to the legally marketed Predicate, OrthoPediatrics PediFlex™ Flexible Nail System (K082375). Implants and accessories included in the Orthofix MJ-FLEX THE NEW METAIZEAU NAIL™ and the predicate device are both Smooth or threaded metallic bone fastener as defined in 21 CFR 888.3040. They are both elastic nails for internal fixation. The Orthofix MJ-FLEX THE NEW METAIZEAU NAIL™ is substantially equivalent to the predicate device in indications for use, site of application, patient population, conditions of use, mechanical performances, basic design, operating principles, materials. The Orthofix MJ-FLEX THE NEW METAIZEAU NAIL™ is similar to its predicate in size and range of variants. Testing in accordance with ASTM F 1264 shows the mechanical strength of the subject device to be 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 Predicates. Clinical data was not needed to support the safety and effectiveness of the Subject Device. The following mechanical testing was performed: • ASTM F 1264–16e1 “Standard Specification and Test Method for Intramedullary Fixation Devices” Furthermore, bacterial endotoxin testing was conducted on the Subject Device, and was found to meet the expected endotoxin limits.

Conclusion	Based on design, materials, indications for use, technological characteristics, and comparison to predicate devices, the Subject Orthofix MJ-FLEX THE NEW METAIZEAU NAIL™ has been shown to be substantially equivalent to legally marketed predicate device, and is safe and effective for its intended use.