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

April 23, 2018

Re: K172699
Trade/Device Name: Agile Nail
Regulation Number: 21 CFR 888.3020
Regulation Name: Intramedullary Fixation Rod
Regulatory Class: Class II
Product Code: HSB
Dated: March 23, 2018
Received: March 26, 2018

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K172699

Device Name
Agile Nail

Indications for Use *(Describe)*
The Agile Nail is intended for insertion in the medullary canal of a femur for the alignment and the stabilization of fractures, and for the correction of deformities.
It is indicated for the treatment of subtrochanteric fractures and of femoral shaft fractures, in pediatric patients, with the exception of newborns and infants, and in adult patients with an appropriate medullary canal.
The indications include:
prophylactic nailing of impending pathologic fractures;
fixation of femurs that have been surgically prepared (osteotomy);
nonunions and malunions;
reconstruction following tumor resection and grafting and bone lengthening and shortening.

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
Telephone	+ 39 045 6719.000
Fax	+ 39 045 6719.380
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	August 29, 2017
Trade Name	Agile Nail
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

Predicate Device Name	**510(k) Number**	**Manufacturer**
Synthes Adolescent Lateral Entry Femoral Nail System	K070843	Synthes(USA)
Orthopediatrics PediNal Intramedullary Nailing System	K083726	Orthopediatrics, Corp.

Device description	The Agile Nail consists of ante grade intramedullary nails, end caps and screws, and related instrumentation for insertion and extraction of the implantable components. The System is designed to address femoral fractures and deformity corrections procedures.
Indications for use	The Agile Nail is intended for insertion in the medullary canal of a femur for the alignment and the stabilization of fractures, and for the correction of deformities. It is indicated for the treatment of subtrochanteric fractures and of femoral shaft fractures, in pediatric patients, with the exception of newborns and infants, and in adult patients with an appropriate medullary canal. The indications include: prophylactic nailing of impending pathologic fractures; fixation of femurs that have been surgically prepared (osteotomy); nonunions and malunions; reconstruction following tumor resection and grafting and bone lengthening and shortening.

Technological Characteristics and Substantial Equivalence	Documentation was provided to demonstrate that the Agile Nail is substantially equivalent to the legally marketed predicates. Components included in the Subject system and the predicates are all dedicated to internal fracture fixation procedure, as defined in 21 CFR 888.3020. The Agile Nail is substantially equivalent to the predicate devices in: intended use, site of application, patient population, conditions of use, mechanical performances, operating principles and materials. Mechanical testing demonstrate how the mechanical properties of the Subject Device are equivalent / better than the predicate involved.
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 Agile Nail was therefore found to be substantially equivalent to the predicate involved in the performance. Clinical data were not needed to support the safety and effectiveness of the Subject Device. Mechanical testing were performed according to the following standards: ASTM F1264-16 “Standard Specification and Test Methods for Intramedullary Fixation Devices”. ASTM F543-17 “Standard Specification and Test Methods for Metallic Medical Bone Screws.”
Biocompatibility data	In order to establish the Subject device non-pyrogenicity, some tests were performed on an equivalent System implants, 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 test reports and test rationale references list: • 166699_rep_fin dated 2016/10/07 • 166700_Report_final dated 2016/10/13 • 16VA00533 validation report dated 2016/10/13 • Cert_2016_7505, Cert_2016_7506, and Cert_2016_7507 report dated 2016/10/19 • AGILE_QE_RA03_R1
Conclusion	Based upon similarities in: intended use, site of application, conditions of use, operating principles and mechanical performances, the Agile Nail has been shown to be substantially equivalent to its legally marketed predicate devices.