Orthofix S.r.l.
Elvira Taccarelli
Regulatory Affairs Manager
Via Delle Nazioni, 9
Bussolengo (VR), IT 37012
Italy

March 22, 2024

Re: K232169
Trade/Device Name: FITBONE® Transport and Lengthening System
Regulation Number: 21 CFR 888.3020
Regulation Name: Intramedullary fixation rod
Regulatory Class: Class II
Product Code: HSB
Dated: March 13, 2024
Received: March 13, 2024

Dear Elvira Taccarelli:

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 (the 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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Farzana Sharmin -S

Digitally signed by Farzana Sharmin -S
Date: 2024.03.22 15:20:00 -04'00'

Farzana Sharmin, PhD
Assistant Director
DHT6A: Division of Joint Arthroplasty Devices
OHT6: Office of Orthopedic Devices
Office of Product Evaluation and Quality
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: 06/30/2023
See PRA Statement below.

Submission Number *(if known)*

K232169

Device Name

FITBONE® TRANSPORT AND LENGTHENING SYSTEM

Indications for Use *(Describe)*

"FITBONE Transport and Lengthening system" is indicated for limb lengthening, open and closed fracture fixation, pseudoarthrosis, malunions, non-unions, or bone transport of the long bones. The "FITBONE Transport and Lengthening system" is indicated for adult only.

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.

510(K) SUMMARY

ORTHOFIX SRL
FITBONE® Transport and Lengthening System

Submitter information

Company Name:	Orthofix S.r.l.
Address	Via Delle Nazioni, 9 37012 Bussolengo (VR) - Italy
Telephone	+39 045 6719000
Fax	+39 045 6719380

Contact Person	Elvira Taccarelli Regulatory Affairs Manager
Address	Via Delle Nazioni, 9 37012 Bussolengo (VR) - Italy
Telephone	+39 045 6719000
Fax	+39 045 6719380
Email address	elviratacarelli@orthofix.it
Date prepared	2024, January 31

Trade Name, Common Name, Classification

Trade Name: FITBONE® Transport and Lengthening System
Common Name: Intramedullary lengthening nail
Classification Name: Intramedullary fixation rod
Regulation Number: 21 CFR 888.3020
Product Code: HSB
Classification: Class II
Panel code: Orthopedic

Primary Predicate and additional predicate device

Primary Predicate	**510(k) Number**	**Manufacturer**
Precice® Bone Transport System	K201567	NuVasive Specialized Orthopedics Inc.
Additional predicate	**510(k) Number**	**Manufacturer**
FITBONE® TAA	K203399	Orthofix s.r.l.

Reference devices

Reference Devices	**510(k) Number**	**Manufacturer**
Orthofix Femoral Nailing system	K973944	Orthofix s.r.l.
Orthofix Tibial Nailing system	K961027	Orthofix s.r.l.

Device description	The subject "FITBONE® Transport and Lengthening System" is indicated for limb lengthening, open and closed fracture fixation, pseudoarthrosis, malunions, non-unions, or bone transport of the long bones. The Fitbone Transport and Lengthening System is indicated for adult only. The subject "FITBONE® Transport and Lengthening System" consists of the implantable intramedullary transport or lengthening nail and its trial nail accessories. The Subject device is implanted into the medullary canal of the femur or tibia and connected to the additional predicate intracutaneous Receiver by a bipolar feed line. The external FITBONE Control Set is identical to that previously cleared for the additional predicate Fitbone TAA device (K203399) and consists of a control electronics station and transmitter. There are no changes to this previously cleared Control Sets and Receiver as a result of this submission. The power required for the distraction process is controlled by hermetically enclosed motor which draws the telescope apart. The electro-magnetic field sent from the Transmitter to the Receiver is converted in the Receiver into DC-Voltage to supply the motor of the FITBONE Transport and Lengthening Nail with voltage, when actioned. The subject nail is anchored to the bone by locking screws through medial-lateral and AP holes in the nail depending on the configuration holes in the nail. The energy needed for the distraction process is transmitted from the outside by placing the external transmitter over the implanted receiver, which is placed in the subcutaneous tissue during surgery. There is no transcutaneous contact between the implanted intramedullary nail and the outer surface of the patient's body. The subject trial nails accessories are available for each size model of the FITBONE Transport (TN) and FITBONE Transport or Lengthening (TLN) nails and are used to simulate the shape of the implant. The subject nails and trial nails are provided in sterile conditions only and are made from, as follows: • Nail: implant grade stainless steel 1.4441, according to ASTM F138-13 "Standard Specification for Wrought 18Chromium-14Nickel-2.5Molybdenum Stainless Steel Bar and Wire for Surgical Implants (UNS S31673)", and Silicone Nusilmed (NuSil MED-4870, NuSil MED-1511, Nusil MED 4750). • Trial nail: implant grade stainless steel 1.4441, according to ASTM F138-13 "Standard Specification for Wrought 18Chromium-14Nickel-2.5Molybdenum Stainless Steel Bar and Wire for Surgical Implants (UNS S31673)" and ASTM F899-20 Standard Specification for Wrought Stainless Steels for Surgical Instruments For the implantation and removal of the subject device the same instruments of the additional predicate Fitbone TAA (K203399) may be used.
Indications for use	"FITBONE Transport and Lengthening system" is indicated for limb lengthening, open and closed fracture fixation, pseudoarthrosis, malunions, non-unions, or bone transport of the long bones. The "FITBONE Transport and Lengthening system" is indicated for adult only.
Technological Characteristics	The following table provides a comparison and assessment of fundamental scientific principles and technological characteristics of the subject, primary predicate and additional predicate devices. Any differences have been demonstrated to not raise new issues of safety or performance by virtue of objective evidence (e.g., bench testing, process validations, etc.). Therefore, the technological characteristics of the subject FITBONE® Transport and Lengthening system are equivalent to the primary predicate Precice® Bone Transport System

	(K201567) and the additional predicate device FITBONE® TAA (K203399).

	Technological Characteristic	Subject Device (Fitbone Bone Transport and Lengthening System)	Primary Predicate Device (Precice Bone Transport System, K201567)	Additional Predicate Device (Fitbone TAA, K203399)
1.	Indications for Use	Indicated for limb lengthening, open and closed fracture fixation, pseudoarthrosis, malunions, non-unions, or bone transport of the long bones. The Fitbone Transport and Lengthening System is indicated for adults only.	Indicated for limb lengthening, open and closed fracture fixation, pseudoarthrosis, malunions, non-unions, or bone transport of the long bones	Intended for limb lengthening of the femur and tibia. Indicated for adult and pediatric (greater than 12 through 21 years of age) patients
	Assessment: The subject indications are identical to the primary predicate and carry the same lengthening indication as the additional predicate. Equivalent - no significant new issues have been raised.			
2.	Anatomical Sites	Long bones	Long bones	Femur, tibia
	Assessment: The anatomical sites for use are identical to primary predicate and similar to additional predicate (femur and tibia are long bones). Equivalent - no significant new issues raised.			
3.	Nail Material	Implant Grade Stainless Steel (1.4441, 316LVM)	Implant Grade Stainless Steel (ASTM F2229, Biodur 108)	Implant Grade Stainless Steel (1.4441, 316LVM)
	Assessment: Subject material is similar to primary predicate and identical to additional predicate. Both have been demonstrated to be biocompatible implant grade stainless steels with unique corrosion properties. Equivalent - no significant new issues raised.			
4.	Nail Size Range	290-490mm in length; 11 and 13mm diameters in varying configurations	280-400mm in length; 10, 11.5, and 13mm diameters in varying configurations	200-245mm in length; 9, 11, and 13mm diameters in varying configurations
	Assessment: Size ranges of subject are similar to primary and additional predicate. Potential performance differences arising from variations in size offerings have been demonstrated through bench testing to not raise significant new issues. Further mitigation is provided through weight bearing precautions in labeling. The ranges are therefore equivalent.			
5.	Maximum Stroke Length Available	80mm	100mm	80mm
	Assessment: The subject stroke length is within that of primary predicate and identical to the additional predicate. Equivalent - no significant new issues raised.			
6.	Method of Distraction/Energy Source	Internal motor electro-magnetically induced by an external transmitter with signal received through a receiver placed just under skin	Internal magnetically powered telescopic feature with two rotating magnets induced by an external controller	Internal motor electro-magnetically induced by an external transmitter with signal received through a receiver placed just under skin

	Assessment: Subject distraction methodology is similar to primary predicate and identical to additional predicate. Differences in technology have been demonstrated through bench testing to not raise significant new issues. The methods are therefore equivalent.			
7.	Sterilization Method	Gas Plasma	Gamma	Gas Plasma
	Assessment: Subject is similar to primary predicate and identical to additional predicate. Supporting process validation demonstrates that there are no new issues raised by the differences in methodology. The sterilization methods are therefore equivalent.			

Performance Analysis	Mechanical testing of the subject devices to demonstrate equivalence in function and safety for the intended use of the FITBONE® Transport and Lengthening nails and trial nails in respect to its additional predicate FITBONE® TAA (K203399) have been performed for the following functional attributes and are included in section "Bench Testing" of this eSTAR application form, as below: • Implantable rod: Static 4-point bending test (with Subject FITBONE® Transport and Lengthening nail) performed according to ASTM F1264-16 - Standard Specification and Test Methods for Intramedullary Fixation Devices, • Implantable rod: Fatigue 4-point bending test (with Subject FITBONE® Transport and Lengthening nail) performed according to ASTM F1264-16 - Standard Specification and Test Methods for Intramedullary Fixation Devices. The Fatigue limit calculation are, instead, performed according to ISO 12107:2012 - Metallic materials — Fatigue testing — Statistical planning and analysis of data, • Implantable rod: Torsional test (with Subject FITBONE® Transport and Lengthening nail) performed according to ASTM F1264-16 - Standard Specification and Test Methods for Intramedullary Fixation Devices, • Implantable rod: Absorbed current by the nail's motor during usage when different forces are applied (with Subject FITBONE® Transport and Lengthening nail). The test performed does not refer to any standard since it is designed for this specific component. The test requires the measurement of the current consumption of the motor while running to obtain a displacement when different forces are applied to the actuator.
Conclusion	Based upon equivalences in: intended use, patient population, site of application, conditions of use, operating principles, and the non-clinical performance data, the subject FITBONE® Transport and Lengthening System have been shown to be substantially equivalent to the legally marketed predicate device.