April 10, 2025

Orthofix srl
Elvira Taccarelli
Regulatory Affairs Manager
Via delle Nazioni, 9
Bussolengo, VR 37012
Italy

Re: K250112
Trade/Device Name: FitboneTM Trochanteric
Regulation Number: 21 CFR 888.3020
Regulation Name: Intramedullary fixation rod
Regulatory Class: Class II
Product Code: HSB
Dated: January 16, 2025
Received: March 27, 2025

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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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: 2025.04.10 12:58:52 -04'00'

Farzana Sharmin, PhD
Assistant Director
DHT6A: Division of Joint Arthroplasty Devices
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Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K250112

Device Name

FitboneTM Trochanteric

Indications for Use *(Describe)*

FitboneTM Trochanteric is indicated for limb lengthening of the femur.
FitboneTM Trochanteric is indicated for adult and pediatric (greater than 12 through 21 years of age) patients.

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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510(K) SUMMARY

ORTHOFIX SRL
FITBONE™ TROCHANTERIC

Submitter information

Company Name:	Orthofix S.r.l.
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Date prepared	2025, January 16th

Trade Name, Common Name, Classification

Trade Name: Fitbone™ Trochanteric
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 reference devices

Primary Predicate	510(k) Number	Manufacturer
Fitbone™ Trochanteric	K233867	Orthofix s.r.l.

Reference Devices	510(k) Number	Manufacturer
FITBONE® TAA	K203399	Orthofix s.r.l.
PRECICE® Intramedullary Limb Lengthening System	K220234	NuVasive Specialized Orthopedics Inc.

Device description	Fitbone™ Trochanteric is a fully implantable intramedullary lengthening nail and accessories. The subject Fitbone Trochanteric consists of the implantable intramedullary lengthening nail and accessories (Locking screws, Trial nails K-wire and Convenience kits). The subject device is implanted into the medullary canal of the femur and connected to the primary predicate intracutaneous Receiver (K203399) by a bipolar feed line. The external FITBONE Control Set is the same as previously cleared for the reference device Fitbone TAA (K203399) and consists of a control electronics station and transmitter. There are no changes to the 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 subject Fitbone Trochanteric Nails with voltage, when actioned. The subject Fitbone Trochanteric Nails are available in two different diameter models (D09mm, D11mm), different lengths and lengthening capabilities. The subject nail is anchored to the bone by locking screws. The locking screws to be used with the subject nails are the same as cleared for the primary predicate Fitbone Trochanteric (K233867) and are available in two variants (standard locking screws and revision locking screws), in two diameters, D4.5mm and D4mm, and in multiple lengths. 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 variant of the Fitbone Trochanteric nails and are used to simulate the shape of the implant. The Fitbone Trochanteric nail and K-wire are provided in sterile conditions only. The trial nails are provided in non-sterile version only. The locking screws are available in both sterile and non-sterile versions. The subject Fitbone Trochanteric Nails and their accessories are made from, as follows: • Nail: implant grade stainless steel 1.4441 (AISI 316LVM), 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, NUSIL MED1-161, NUSIL MED2-4502). • Trial nail: implant grade stainless steel 1.4441 (AISI 316LVM), 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. • Locking screws (cleared in K233867): 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)"

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	• K-wire (cleared in K233867): 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)" The subject device, as the primary predicate, will be implanted only by Healthcare Professionals (HCP), with full awareness of the appropriate orthopedic procedures (including application and removal), in the operating theatre only. The limb distraction of the femur treatment will be activated in home by the patient or clinic theatres. The reason for the submission is to introduce a design change to the Fitbone Trochanteric nail cleared in K233867.
Indications for use	Fitbone™ Trochanteric is indicated for limb lengthening of the femur. Fitbone™ Trochanteric is indicated for adult and pediatric (greater than 12 through 21 years of age) patients.
Comparison of Technological Characteristics with the Predicate Device	The following table provides a comparison of technological characteristic of the subject and primary predicate device. Any differences have been demonstrated not to raise different questions of safety and effectiveness by virtue of objective evidence.

Technological Characteristic		**Subject Device (Fitbone Trochanteric)**	**Predicate Device (Fitbone Trochanteric, K233867)**
1.	Intended use and Indications for Use	Fitbone™ Trochanteric is indicated for limb lengthening of the femur. Fitbone Trochanteric is indicated for adult and pediatric (greater than 12 through 21 years of age) patients.	Fitbone™ Trochanteric is indicated for limb lengthening of the femur. Fitbone Trochanteric is indicated for adult and pediatric (greater than 12 through 21 years of age) patients.
		Assessment: The intended use and indications for use for the subject device are the same of the primary predicate device.	
2.	Anatomical Sites	Femur	Femur
		Assessment: The anatomical sites for use of the subject device is the same of the primary predicate device.	
3.	Intended environment	Clinic or Home environment	Clinic or Home environment
		Assessment: The intended environment is the same as the primary predicate.	
4.	Nail Material	Implant Grade Stainless Steel (1.4441, AISI 316LVM) and Silicone Nusilmed	Implant Grade Stainless Steel (1.4441, AISI 316LVM) and Silicone Nusilmed
		Assessment: Subject materials identical to primary predicate.	
5.	Nail Size Range	217-357mm in length; 9 and 11mm diameters in varying configurations	225-365mm in length; 9 and 11mm diameters in varying configurations
		Assessment: Diameter size ranges are the same to primary predicate device. Maximum length is within the length range of the primary predicate device. Minimum length is within the length range of the chosen reference devices. Potential performance differences arising from variations in size offerings was analyzed through bench testing, performed on subject, predicate device and reference devices.	

6.	Maximum distraction possible	From 40mm (with nail length 217mm) to 80mm (with longer nails)	From 40mm (with nail length 225mm) to 80mm (with longer nails)
		Assessment: The maximum distraction possible of the Subject device is equivalent to the primary predicate. The worst-case scenario (maximum distraction possible of 80 mm) is identical to the primary predicate device.	
7.	Tail Nail Geometry	2 holes	3 holes
		Assessment: Bench testing results prove substantial equivalency with predicate devices.	
8.	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 motor electro-magnetically induced by an external transmitter with signal received through a receiver placed just under skin
		Assessment: Subject distraction methodology is identical to primary predicate.	
9.	Sterilization Method	Gas Plasma	Gas Plasma
		Assessment: The sterilization method is identical to the primary predicate.	

Performance Data	Subject devices have similar configuration, material, sizes, and design to the primary predicate Fitbone Trochanteric (K233867) and the reference devices. The following mechanical testing was performed on the subject implantable nails: • Static cantilever bending test for subject Fitbone Trochanteric nails (with new tail left design) in comparison with the original design cleared in K233867 and with reference device PRECICE Intramedullary Limb Lengthening System (K220234). The subject device introduces a design change to the implantable intramedullary lengthening nails cleared in K233867. The only change to the subject device in comparison to the original design cleared in K233867 is a modification to screw holes in the distal tail of the nail. This design change does not affect results of testing presented in K233867, and results of that testing are still applicable to the subject device.
Conclusions	Based upon: intended use, device design, patient population, site of application, conditions of use, operating principles, and the non-clinical performance data, the subject Fitbone Trochanteric has been shown to be substantially equivalent to the legally marketed primary predicate device Fitbone Trochanteric cleared in K233867.