May 8, 2026

Orthofix Srl
Chiara Zuliani
Senior Technical Product RA Specialist
Via Delle Nazioni, 9
Bussolengo (Vr), IT 37012
Italy

Re: K253991
Trade/Device Name: Fitbone™ Trochanteric, FITBONE® Transport and Lengthening System, FITBONE® TAA
Regulation Number: 21 CFR 888.3020
Regulation Name: Intramedullary Fixation Rod
Regulatory Class: Class II
Product Code: HSB
Dated: April 7, 2026
Received: April 9, 2026

Dear Chiara Zuliani:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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

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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K253991

Please provide the device trade name(s).

FITBONE™ TROCHANTERIC
FITBONE® TAA
FITBONE® TRANSPORT AND LENGTHENING SYSTEM

Please provide your Indications for Use below.

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® TAA is an intramedullary lengthening system for limb lengthening of the femur and tibia. The FITBONE®TAA intramedullary lengthening system is indicated for adult and pediatric (greater than 12 through 21 years of age) patients.

The 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.

Please select the types of uses (select one or both, as applicable).

- ☒ Prescription Use (21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

510(K) SUMMARY

ORTHOFIX SRL
FITBONE™ TROCHANTERIC - FITBONE® TAA - FITBONE® TRANSPORT AND LENGTHENING SYSTEM

Submitter information

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Email address	chiarazuliani@orthofix.it
Date of submission	2025, December 12

Trade Name, Common Name, Classification

Trade Name:	Fitbone™ Trochanteric, FITBONE® Transport and Lengthening System, FITBONE® TAA
Common Name:	Rod, Fixation, Intermedullary and Accessories
Regulation description:	Intermedullary Fixation rod
Regulation Number:	21 CFR 888.3020
Product Code:	HSB
Classification:	Class II
Panel code:	Orthopedic

Predicate devices and additional predicate device

Primary Predicate	**510(k) Number**	**Manufacturer**
Fitbone™ Trochanteric	K233867	Orthofix s.r.l.
Additional Predicates	**510(k) Number**	**Manufacturer**
FITBONE® TAA	K203399	Orthofix s.r.l.
Fitbone Transport and Lengthening System	K232169	Orthofix s.r.l.

Device description	The subject Implantable bone screws are a line extension of the existing primary predicate screws already cleared under K233867.

	The current submission is a bundled submission and the purpose of the current submission is to gain clearance for the Orthofix Implantable Bone Screws that are compatible and are line extension of the screws previously cleared with the above identified previously cleared Fitbone systems (Fitbone™ Trochanteric - K233867, FITBONE® TAA - K203399 and K163368, Fitbone Transport and Lengthening System - K232169). The subject Orthofix implantable screws consist of the implantable bone screws components used in conjunction with Orthofix Fitbone nailing devices. The subject implantable bone screws are available in different thread designs, thread and shaft diameters and lengths. The most appropriate implantable device size and length is selected according to anatomical, bone dimension and quality, soft tissue dimensions. Application and removal of Implantable screws can be performed with Orthofix general orthopedic instrumentation. The subject screws, as the predicate screws, are available in both sterile and non-sterile versions. The subject devices, as the primary predicate, will be implanted only by Healthcare Professionals (HCP), with full awareness of the appropriate orthopedic procedures and familiarity with the devices, instruments and surgical procedures (including application and removal). The subject Orthofix implantable screws are made from implant grade stainless steel, conforming to ASTM F138 “Standard Specification for Wrought 18Chromium-14Nickel-2.5Molybdenum Stainless Steel Bar and Wire for Surgical Implants (UNS S31673)”. Labelling reflects the materials.
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® TAA is an intramedullary lengthening system for limb lengthening of the femur and tibia. The FITBONE®TAA intramedullary lengthening system is indicated for adult and pediatric (greater than 12 through 21 years of age) patients. The 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 characteristic of the subject, primary and additional predicate devices. Any differences have been demonstrated not to raise new issues of safety or performance by virtue of objective evidence (e.g., bench testing, process validations, etc.). Therefore, *technological characteristics* of the Subject Orthofix® Implantable Bone Screws are substantially equivalent to the cleared screws of the primary predicate Fitbone™ Trochanteric (K233867) and the additional predicates Fitbone systems.

Technological Characteristic	Subject Device Orthofix® Implantable Bone Screws compatible with Fitbone systems	Predicate Device Fitbone™ Trochanteric, K233867)	Additional Predicate Device (Fitbone TAA, K203399-)	Additional Predicate Device (Fitbone Transport and Lengthening System, K232169)

1	Material	Stainless steel (1441-AISI 316L)	Locking screws are made from stainless steel (1441-AISI 316L)	Locking screws are made from stainless steel (1441-AISI 316L)	The screws used for Fitbone Transport and Lengthening System are the same screws cleared under Fitbone Trochanteric (K233867)
		Assessment: The material is the same as the primary and additional predicates. Equivalent - no significant new issues raised.			
2	Sterilization Method	Gamma radiation	Gamma radiation for sterile Locking screws	Locking screws are provided in not sterile configuration	The screws used for Fitbone Transport and Lengthening System are the same screws cleared under Fitbone Trochanteric (K233867)
		Assessment: The subject screws are sterilized by gamma radiation as per standard sterilization method for all Orthofix cleared portfolio that is validated and the sterilization cycle is designed to provide a minimum sterility assurance level (SAL) of 10-6. Equivalent - no significant new issues raised.			
3	Screw diameter	Ø4,5mm peg screw (locking and revision)	Ø4,5mm peg screw (locking and revision) Ø4,0mm peg screw (locking and revision)	Ø4,5mm pegs short thread Ø4,5mm pegs long thread Ø4,0mm pegs	The screws used for Fitbone Transport and Lengthening System are the same screws cleared under Fitbone Trochanteric (K233867)
		Assessment: The subject screw diameters are equivalent to the diameter of the primary and additional predicates. Equivalent - no significant new issues raised.			
4	Screw lengths	Ø4,5 -> 85-110mm (5mm incremt)	Ø4,0 -> 20-80mm (2,5mm incremt) Ø4,5 -> 20-80mm (2,5mm incremt)	Ø4,5mm pegs short thread 20-50mm (5mm increments) Ø4,5mm pegs long thread 20-110mm (5mm increments) Ø4,0mm pegs 20-35mm (5mm increments)	The screws used for Fitbone Transport and Lengthening System are the same screws cleared under Fitbone Trochanteric (K233867)
		Assessment: The subject screw lengths are partially equivalent to the length of the additional predicate screws and are within the length range of the additional predicate Fitbone TAA. Supporting verification activities demonstrates that there are no new issues raised by the differences in screw lengths. The screw lengths are therefore equivalent.			
5	Screw threads	Double thread (under the screw head and on the tip)	Double thread (under the screw head and on the tip)	Single thread (under the screw head)	The screws used for Fitbone Transport and Lengthening System are the same screws cleared under Fitbone

					Trochanteric (K233867)
		Assessment: The position of the threads in the subject screws is equivalent to the position of the threads in the primary predicate. Equivalent - no significant new issues raised.			

Performance Analysis	Bench testing was not performed for the subject Orthofix Implantable Bone screws because the subject new screws are a line extension of the existing primary predicate screws already cleared under the K233867. The subject new sizes for the double threaded locking screws were designed by modifying only the length of the screw and not the thread itself, hence, all thread-related performances are not impacted by the new design and the existing test reporting is still applicable for the subject new screws. In terms of length, the new screws do not introduce a new worst case since the same length is available for the existing Fitbone Locking screws already cleared under K203399. Only difference between the designs of the subject screws and existing Fitbone Locking screws (K203399) is the thread which is already covered by the existing test reporting.
Pyrogenicity Data	In order to establish the Subject device non-pyrogenicity, tests were performed according to the following international standards and guidance: • USP 40 - NF35: 2017 < 85 > “Bacterial Endotoxins Test (LAL)”; • USP 40 – NF35: 2017 < 161 > “Medical Devices – Bacterial Endotoxins and Pyrogen Tests”; • ANSI / AAMI ST72: 2016 “Bacterial endotoxins – Test methodologies, routine monitoring and alternative batch testing”; • FDA 2012 Q&A “Guidance for Industry Pyrogen and Endotoxins Testing: Question and Answers”.
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 device is substantially equivalent to the legally marketed predicate device.