May 19, 2026

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

Re: K260146
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: April 16, 2026
Received: April 17, 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 Management System Regulation (QMSR) (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.	K260146

Please provide the device trade name(s).

FITBONE® TRANSPORT AND LENGTHENING SYSTEM

Please provide your Indications for Use below.

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® 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	Chiara Zuliani Senior Technical Product RA Specialist
Address	Via Delle Nazioni, 9 37012 Bussolengo (VR) - Italy
Telephone	+39 045 6719000
Fax	+39 045 6719380
Email address	chiarazuliani@orthofix.it
Date of submission	2026, January 19

Trade Name, Common Name, Classification

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

Predicate devices and additional reference device

Primary Predicate	**510(k) Number**	**Manufacturer**
FITBONE® Transport and Lengthening System	K232169	Orthofix s.r.l.
Reference Device	**510(k) Number**	**Manufacturer**
FITBONE® TAA	K163368	Orthofix s.r.l.
	K203399	

Device description	The subject Fitbone® transport and lengthening system consists of the implantable intramedullary pulling transport nails and is a line extension of the existing primary predicate Fitbone® transport and lengthening nails (K232169). The Subject device is implanted into the medullary canal of the femur or tibia and connected to the additional predicate/reference device intracutaneous Receiver (K203399 and K163368) by a bipolar feed line. The external FITBONE Control Set is identical to that previously

	cleared for the additional predicate/reference device Fitbone TAA device (K203399, K163368) and consists of a control electronics station and transmitter. 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® transport and lengthening nails with voltage, when actioned. The 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 nails, as the primary predicate Fitbone® transport and lengthening system, in same sterile conditions are made from implant grade stainless steel 1.4441, according to ASTM F138 "Standard Specification for Wrought 18Chromium-14Nickel-2.5Molybdenum Stainless Steel Bar and Wire for Surgical Implants (UNS S31673)", and medical grade Silicone. The Subject, as the predicates, 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 and tibia treatment will be activated in home by the patient or clinic theatres. The retraction mode of the intramedullary nail will be operated only by HCPs, in case of unintended over-distraction or if nail Rewind & Go is needed as per pre-operative plan.
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 characteristic of the subject, primary and additional reference device. Any differences have been demonstrated not to raise different issues of safety or performance by virtue of objective evidence (e.g., bench testing, process validations, etc.). Therefore, *technological characteristics* of the new Subject Fitbone® transport and lengthening nails are substantially equivalent to the primary predicate Fitbone® transport and lengthening system (K232169) and reference device.

Technological Characteristic		Subject Device (Fitbone® transport and lengthening system)	Predicate Device Fitbone® transport and lengthening system, K232169)	Additional Reference Device (Fitbone TAA, K163368 and K203399)
1	Nail Material	Stainless steel (1441-AISI 316LVM)	Stainless steel (1441-AISI 316LVM)	Stainless steel (1441-AISI 316LVM)
		Assessment: The material is the same as the primary and reference predicates. Equivalent - no different questions of safety and effectiveness raised.		
2		H_2O_2 Plasma	H_2O_2 Plasma	H_2O_2 Plasma

	Sterilization Method	Assessment: the subject´s device sterilization method (H_2O_2 plasma) is equivalent to the primary predicate and to additional predicate/reference device. Equivalent - no different questions of safety and effectiveness raised		
3	Nail Size Range	290-490mm in length; 11 and 13mm diameters in varying configurations	290-490mm in length; 11 and 13mm diameters in varying configurations	Not applicable
		Assessment: Size ranges of subject devices are equivalent to the primary. Equivalent - no different questions of safety and effectiveness raised		
4	Maximum Bone Transport Stroke Available	80 mm	80 mm	Not applicable
		Assessment: The transport stroke length of the subject device is the same of the primary predicate. Equivalent - no different questions of safety and effectiveness raised		
5	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	Internal motor electro-magnetically induced by an external transmitter with signal received through a receiver placed just under skin
		Assessment: Subject distraction methodology is equivalent to the primary and reference devices. Equivalent - no different questions of safety and effectiveness raised		
Performance Analysis		Mechanical testing/rationale of the subject devices to demonstrate equivalence in function and safety for the intended use of the subject Fitbone Transport Pulling nails in respect to the existing primary predicate Fitbone® transport and lengthening nails (K232169) have been performed for the following functional attributes: • Implantable rod: Inverted Load test for pulling nails with subject Fitbone Transport Pulling nails, • Implantable rod: Static 4-point bending test performed according to ASTM F1264-16 - Standard Specification and Test Methods for Intramedullary Fixation Devices on the primary predicate Fitbone® transport and lengthening nails (K232169) is deemed applicable to the subject devices, • Implantable rod: Fatigue 4-point bending test performed according to ASTM F1264-16 - Standard Specification and Test Methods for Intramedullary Fixation Devices on the primary predicate Fitbone® transport and lengthening nails (K232169) is deemed applicable to the subject devices, • Implantable rod: Torsional test performed according to ASTM F1264-16 - Standard Specification and Test Methods for Intramedullary Fixation Devices on the primary predicate Fitbone® transport and lengthening nails (K232169) is deemed applicable to the subject devices,		

Conclusion	Based upon equivalences in: intended use, patient population, site of application, conditions of use, operating principles, and the non-clinical performance data, the new nail model of FITBONE® Transport and Lengthening System have been shown to be safe and effective and to perform equivalently as compared to the legally marketed predicate device. Therefore, the subject new nail model of FITBONE® Transport and Lengthening System is substantially equivalent to the legally marketed predicate devices and the reference device chosen as basis for the scientifical methodology.

Via delle Nazioni 9 | 37012 Bussolengo | Verona, Italy
+39.045.6719000
orthofix.com