December 3, 2024

Orthofix S.r.l.
Elvira Taccarelli
Regulatory Affairs Manager
Via delle Nazioni, 9
Bussolengo, IT 37012
Italy

Re: K242861
Trade/Device Name: TrueLok™ Elevate
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/Multiple Component Metallic Bone Fixation Appliances And Accessories
Regulatory Class: Class II
Product Code: KTT
Dated: September 20, 2024
Received: September 20, 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.

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,

Lixin Liu -S

Lixin Liu, Ph.D
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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K242861

Device Name

TrueLok Elevate

Indications for Use *(Describe)*

TrueLok Elevate is intended for treatment of non-union or pseudoarthrosis of long bones and correction of bony or soft tissue defects or deformities.
The TrueLok Elevate is indicated for adult and pediatric (greater than 2 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.

510(K) SUMMARY

ORTHOFIX SRL
TRUELOK™ ELEVATE

Submitter information

Company Name:	Orthofix S.r.l.
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Date prepared	November 27th, 2024

Trade Name, Classification

Trade Name:	TrueLok™ Elevate
Classification Regulation Nr:	21 CFR 888.3030
Regulation name:	Single/multiple component metallic bone fixation appliances and accessories.
Review Panel:	Orthopedic
Product Code:	KTT
Device Class:	Class II
Device Classification Name:	Appliance, fixation, nail/blade/plate combination, multiple component

Predicate and additional reference devices

Predicate Device	**510(k) Number**	**Manufacturer**
Orthofix TrueLok Hexapod System (TL-HEX) V.2.0	K170650	Orthofix S.r.l.

Reference Devices	**510(k) Number**	**Manufacturer**
TrueLok Monolateral/Bilateral Fixator	K941048	Orthofix S.r.l.
Orthofix Modulsystem	K955848	
Orthofix Femoral Nailing System	K973944	
Orthofix External Fixation Screw (Pin) with Hydroxyapatite Coating	K974186	
Orthofix Titanium Nailing Systems	K053261	
Orthofix Galaxy Fixation System	K113770	
Orthofix Ankle Hindfoot Nailing System	K141571	
Orthofix Chimaera Hip Fracture	K161466	

Device Description	The subject TrueLok Elevate is an external fixation component system (including its accessories) to be used with the Orthofix TrueLok family, for which Orthofix identified as a predicate device TrueLok Hexapod System (TL-HEX) V2.0 (K170650). The subject device consists in a further series of elements for external fixation added to the Orthofix TrueLok family with the aim of supporting the Orthofix TrueLok external fixator systems family falling within the indications for use of the more extensive, cleared indications for use of the chosen predicate device, for the specific use in bone transport treatment. The subject TrueLok Elevate is intended for treatment of non-union or pseudoarthrosis of long bones and correction of bony or soft tissue defects or deformities. The TrueLok Elevate is indicated for adult and pediatric (greater than 2 through 21 years of age) patients. The subject device is constituted by an external fixator and related accessories (half pins, k-wires, drill positioning guide, template and template inserts and convenience kits). The technique for the use of the subject device consists in fixing two half pins on the first cortical of the bone segment that the surgeon decided to transport, and two half pins on both cortexes of the bone. The positioning of the half pins is driven by a template. During the treatment, through the knob present on the device, the bone segment is gradually pulled outward by the patient/caregiver to laterally transport the bone segment. The subject device, as the 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 distraction of the limb will be activated in home by the patient/caregiver or in clinic theatre by the HCP. Treatment activation for pediatric patients in the home environment may require the assistance of a caregiver.
Indications for use	The TrueLok Elevate is intended for treatment of non-union or pseudoarthrosis of long bones and correction of bony or soft tissue defects or deformities. The TrueLok Elevate is indicated for adult and pediatric (greater than 2 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.

Technological Characteristic		**Subject Device TrueLok Elevate**	**Predicate Device Orthofix TrueLok Hexapod System (TL-HEX) V.2.0 (K170650)**
1.	Intended use and indications for Use	The TrueLok Elevate is intended for treatment of non-union or pseudoarthrosis of long bones and correction of bony or soft tissue defects or deformities. The TrueLok Elevate is indicated for adult and pediatric (greater than 2 through 21 years of age) patients.	The TL-HEX System is intended for limb lengthening by metaphyseal or epiphyseal distractions, fixation of open and closed fractures, treatment of non-union or pseudoarthrosis of long bones and correction of bony or soft tissue defects or deformities. Indications, both for adults and all pediatric subgroups except newborns, include:

			- post-traumatic joint contracture which has resulted in loss of range of motion - fractures and disease which generally may result in joint contractures or loss of range of motion and fracture requiring distraction - correction of bony or soft tissue deformities - correction of bony or soft tissue defects - joint arthrodesis - infected fractures or non-unions
		Assessment: The indications for use of the subject device fall within the indications for use of the predicate device.	
2.	Target Population	Adult and pediatric (greater than 2 through 21 years of age) patients.	Adult and pediatric patients with the exception of newborns.
		Assessment: The range of the target pediatric population for the subject device (greater than 2 through 21 years of age) falls within the pediatric patients range of the predicate device.	
3.	Anatomical Sites	Long bones	Long bones
		Assessment: The subject device has the same anatomical application sites in respect to the predicate device.	
4.	Intended environment	Clinic and Home environment	Clinic and Home environment
		Assessment: The subject device has the same intended environment of the predicate device.	
5.	External fixation frame Material	Bars (fixed and sliding): EN-AW 6082 T6 conforming to UNI EN 573	rings: Aluminum (EN 754), struts: Aluminum alloy (EN754), stainless steel (ASTM A276), PEEK
		Assessment: Subject external fixation frame materials are similar to predicate device. Equivalent – no different questions have been raised.	
6.	Half Pins Material	Stainless steel (AISI316LVM;ASTMF138/ISO5832-1)	Stainless steel (AISI316LVM;ASTMF138/ISO5832-1)
		Assessment: Subject half pins material is identical to predicate.	
7.	Half Pins Range	length: 180 mm, diameter: 4.0 - 5.0 - 6.0 mm (already cleared, not subject to this application) length: 120 mm, diameter: 4.0 mm	length: 180 mm diameter: 4.0 - 5.0 - 6.0 mm
		Assessment: The subject half pin length is shorter for the subject device than the predicate device. This does not impact the safety and performance of the subject device since longer length can be considered a worst case for mechanical behavior. Equivalent – no different questions have been raised.	
8.	Sterilization Method (Sterile items)	Gamma radiation	Gamma radiation
		Assessment: The subject device has the same sterilization method as the predicate device for components provided sterile	

Performance Data	The subject devices have similar configuration, materials, sizes, and design in comparison to the predicate Orthofix TrueLok Hexapod System (K170650) and the additional reference device True/Lok Monolateral/Bilateral Fixator (K941048). The following mechanical evaluation was performed for the external frame and the half pins: - Static axial stiffness test for subject TrueLok Elevate external fixator performed according to ASTM F1541-17 Annex 7 “Test Method for External Skeletal Fixator/Constructs Subassemblies”, in comparison with reference device True/Lok Monolateral/Bilateral Fixator (K941048). - Slipping torque on connectors test for subject TrueLok Elevate external fixator performed according to ASTM F1541-17 Annex 2 “Test Method for External Skeletal Fixator Connectors”, in comparison with reference device True/Lok Monolateral/Bilateral Fixator (K941048). - Static 4-point bending evaluation for subject half pins of TrueLok Elevate in comparison to the predicate device Orthofix TrueLok Hexapod System (K170650) - Torsional strength evaluaton for subject half pins of TrueLok Elevate in comparison to the predicate device TrueLok Hexapod System (K170650)
Conclusions	Based upon substantial equivalences in: intended use, patient population, site of application, conditions of use, operating principles, and the non-clinical performance data, the subject TrueLok™ Elevate has been shown to be substantially equivalent to the legally marketed predicate device (K170650).