November 5, 2021

Orthofix SRL
% Cheryl Wagoner
Consultant
Wagoner Consulting LLG
PO Box 15729
Wilmington, North Carolina 28408

Re: K212044
Trade/Device Name: TrueLok™ Evo
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/Multiple Component Metallic Bone Fixation Appliances And Accessories
Regulatory Class: Class II
Product Code: KTT, LXT
Dated: September 24, 2021
Received: September 28, 2021

Dear Cheryl Wagoner:

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 (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 located 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.

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 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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,

Ting Song, Ph.D., R.A.C.
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.

510(k) Number *(if known)*

K212044

Device Name

TrueLok™ EVO

Indications for Use *(Describe)*

The TrueLok™ EVO is intended to provide bone fixation.

The TrueLok™ EVO is indicated for fractures, pseudarthrosis / non-unions, lengthening, joint arthrodesis and correction of bony or soft tissue deformities and defects (e.g. bone transport) in long bones and in the foot.

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
(21 CFR 807.92)

Submitter information

Submitter Name	Orthofix Srl
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Date of preparation	September 14, 2021

Trade Name, Common Name, Classification

Trade Name	TrueLok™ EVO
Device	Appliance, Fixation, Nail/Blade/Plate Combination, Multiple Component
Primary Product code	KTT, LXT
Panel Code	Orthopedic
Class	Class II
Regulation Number	21 CFR 888.3030
Regulation description	Single/multiple component metallic bone fixation appliances and accessories

Predicate devices and reference devices

Primary Predicate Devices	**510(k) Number**	**Manufacturer**
TRUE LOK MONOLATERAL/BILATERAL FIXATOR	K941048	Orthofix S.r.l.
Reference Device		
Orthofix TL-HEX True Lok Hexapod System (TL-HEX)	K152171	Orthofix S.r.l.
ORTHOFIX MODULAR SYSTEM	K944092/ K955848/ K974186	Orthofix S.r.l.
DePuy Synthes MAXFRAME Multi-Axial Correction System	K161417	Synthes USA, LLC

Device description	The TrueLok™ EVO system is a modular circular external fixation system based on Ilizarov fixation apparatus principles. The TrueLok™ consists of external supports (rings and footplates), variable length struts and a variety of connection elements that build the external frame. The TrueLok™ external frame is secured by using the Orthofix predicates pin and wires. The Subject external support

	components (rings, footplates and struts), are made from AISI 316LVM, AISI 630, Aluminum alloy (EN-AW 6082 T6) and Epoxy carbon fiber. Application and removal of the TL-EVO can be performed with Orthofix general orthopedic instrumentation. TrueLokTM EVO fixator components are provided in single-use sterile configuration and they are available as single component packaged in double pouches or in multiple components packaged in double rigid blister.
Indications for use	The TrueLok™ EVO is intended to provide bone fixation. The TrueLok™ EVO is indicated for fractures, pseudarthrosis / non-unions, lengthening, joint arthrodesis and correction of bony or soft tissue deformities and defects (e.g. bone transport) in long bones and in the foot.
Technological Characteristics and Intended Use	The Subject device fundamental scientific principles and technological characteristic, including: the intended use, material and general design, are the same as, or similar to, the chosen predicate devices. Summary of the technological characteristics and Intended Use: ✓ *Intended use*: identical for bone fixation. ✓ *Indications for Use, Anatomical sites, operating principles and conditions of use*: are substantially equivalent to the more extensive application of indications of the predicates; no new risks associated to the Subject device compared to those of the Primary predicates and the additional predicate device which have same indications for use, anatomical sites and conditions of use. Verification activities on Subject devices demonstrated the same safety and effectiveness performs equivalent to the predicate devices. ✓ *Geometry and size*: similar sizes and geometry of the predicates external components; similar sizes and geometry of the predicate bone screws. ✓ *Sterilization*, same method as the predicates. The *technological characteristics* of the TrueLok™ EVO are substantially equivalent to the predicate devices.
Performance Analysis	Subject device has similar configuration, sizes and design as the predicate devices. Performance data was provided in support of the substantial equivalence determination for Magnetic Resonance Imaging (MRI) with respect to the reference predicate device. MRI compatibility testing/assessment was conducted as per the FDA's guidance "Establishing Safety and Compatibility of Passive Implants in the Magnetic Resonance (MR) Environment", December 11, 2014 and the standards listed below: 1. Magnetically induced displacement force (ASTM F2052) 2. Magnetically induced torque (ASTM F2213)

	3. Radiofrequency (RF) induced heating (ASTM F2182) 4. MR image artifact (ASTM F2119) In summary, MR safety testing/assessment supports the appropriate MR parameters and symbols found in the subject device labeling. Performance mechanical testing on Subject components item have been performed according to: ASTM F1541-17 Standard Specification and Test Methods for External Skeletal Fixation Devices. Results to support the determination of substantial equivalence from testing and engineering assessments on worst cases of Subject device and corresponding predicate devices and other similar devices, confirm that Subject device, as safe, as effective, and performs as well as or better than the predicate devices. Any potential hazards have been evaluated and controlled through Risk Management activities, and any relevant information, have been addressed in the labelling, after all control measures have been implemented. The review of the current clinical literature on the predicates and on other similar devices have been conducted to support the clinical indications of TrueLok™ EVO without requiring further clinical data.
Conclusion	Based upon equivalences in: intended use, site of application, conditions of use, operating principles, and the non-clinical performance data, the TrueLok™ EVO has been shown to be safe and effective, and to perform equivalently as compared to the legally marketed predicate devices. Therefore, the Subject device is substantially equivalent to the legally marketed predicate devices.