



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

Orthofix Srl
% Cheryl Wagoner
Consultant
Wagoner Consulting LLC
P O Box 15729
Wilmington, North Carolina 28408

May 10, 2017

Re: K170650
Trade/Device Name: Orthofix TrueLok Hexapod System (TL-HEX) V2.0
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: Class II
Product Code: KTT, OSN
Dated: April 7, 2017
Received: April 11, 2017

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. 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

<http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K170650

Device Name

Orthofix TrueLok Hexapod System (TL-HEX) V2.0

Indications for Use (Describe)

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 fractures requiring distraction
- Open and closed fracture fixation
- Pseudoarthrosis of long bones
- Limb lengthening by epiphyseal or metaphyseal distraction
- Correction of bony or soft tissue deformities
- Correction of bony or soft tissue defects
- Joint arthrodesis
- Infected fractures or non unions

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

Special 510(k) Premarket Notification
Orthofix TrueLok Hexapod System (TL-HEX) V2.0

510(k) Summary
(as required by 21 CFR 807.92)

Submitter	Orthofix Srl
	Via delle Nazioni, 9 37012 Bussolengo (VR) - Italy
Telephone	+ 39 045 6719.000
Fax	+ 39 045 6719.380

Contact Person	Gianluca Ricadona Sr. Quality & Regulatory Affairs Manager
Address	Via delle Nazioni, 9 37012 Bussolengo (VR) - Italy
Telephone	+ 39 045 6719.000
Fax	+ 39 045 6719.380
email	GianlucaRicadona@orthofix.it

Date Prepared	March 1, 2017
---------------	---------------

Trade Name	Orthofix TrueLok Hexapod System (TL-HEX) V2.0
Common Name	Multilateral Fixators and Accessories
Panel Code	87/ Orthopaedic
Classification Name	Single/multiple component metallic bone fixation appliances and accessories
Class	Class II
Regulation Number	21 CFR 888.3030
Product Code	KTT, OSN

Name of Predicate Device	510(k) #	Manufacturer
Orthofix TL-HEX True Lok Hexapod System (TL-HEX) V1.4	K152171	Orthofix Srl

Description	The Subject device is a multilateral external fixation system. The System can also be used with a web-based software component that is designed to be used to assist the physician in creating a patient adjustment schedule that assists in adjusting the six struts. Components of the System include: • Full, 5/8 and 3/8 aluminum Rings • Double Row Footplates • Adjustable struts • Aluminum strut clips (number and direction) • Stainless steel instrumentation such as hex drivers, wrenches, and pliers • Implantable components such as half pins and wires • Web-based software
--------------------	---

Indications and Intended Use	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
-------------------------------------	---

Special 510(k) Premarket Notification
Orthofix TrueLok Hexapod System (TL-HEX) V2.0

	subgroups except newborns, include but are not limited to: • 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 fractures requiring distraction • Open and closed fracture fixation • Pseudoarthrosis of long bones • Limb lengthening by epiphyseal or metaphyseal distraction • Correction of bony or soft tissue deformities • Correction of bony or soft tissue defects • Joint arthrodesis • Infected fractures or non-unions
Technological Characteristics and Substantial Equivalence	Documentation was provided to demonstrate that the Subject device is substantially equivalent to the Predicate Orthofix TL-HEX True Lok Hexapod System (TL-HEX) V1.4 (K152171). The subject device is substantially equivalent to the predicate device in intended use, indications for use, site of application, patient population, condition of use, technological characteristics, materials, mechanical performances and implantable components. The Subject device includes additional hardware components, minor changes to some existing ones and updated software version respect to the predicate.
Performance Data	The potential hazards have been evaluated and controlled through a Risk Management Plan. All testing met or exceeded the requirements, as established by the test protocols and applicable standards. A review of the mechanical data indicates that the hardware components of the Subject device continues to be capable of withstanding expected loads without failure. Additionally, software verification and validation testing were completed, in conformance with FDA's guidance document entitled "General Principles of Software Validation; Final Guidance for Industry and FDA Staff." The results indicate that the updated software continues to perform as intended. The Subject device was therefore found to be substantially equivalent to the Predicate device. Clinical data was not needed to support the safety and effectiveness of the Subject Device. The following mechanical and software testing were performed: • ASTM F1541-02 "Standard Specification and Test Methods for External Skeletal Fixation Devices" • Software IQ, OQ, PQ
Conclusion	Based upon similarities in: intended use, indications for use, site of application, patient population, condition of use, technological characteristics, materials, mechanical performances and implantable components. Orthofix TrueLok Hexapod System (TL-HEX) V2.0 has been shown to be substantially equivalent to the legally marketed predicate device, and to be safe and effective for its intended use.