



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

Orthofix Srl  
% Cheryl Wagoner  
Principal Consultant  
Wagoner Consulting LLC  
PO Box 15729  
Wilmington, North Carolina 28408

September 28, 2015

Re: K152171

Trade/Device Name: Orthofix TL-HEX True Lok Hexapod System (TL-HEX) V1.4

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: July 31, 2015

Received: August 4, 2015

Dear Ms. 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" (21CFR 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 yours,

**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)

K152171

Device Name

Orthofix TL-HEX True Lok Hexapod System (TL-HEX) V1.4

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. 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  
[PRASStaff@fda.hhs.gov](mailto:PRASStaff@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."*

**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 Quality & Regulatory Affairs Manager
Address	Via delle Nazioni, 9 37012 Bussolengo (VR) - Italy
Telephone	+ 39 045 6719.000
Fax	+ 39 045 6719.380
Email	<a href="mailto:gianlucaricadona@orthofix.com">gianlucaricadona@orthofix.com</a>

Date Prepared	September 28, 2015
---------------	--------------------

Trade Name	Orthofix TL-HEX True Lok Hexapod System (TL-HEX) V1.4
Common Name	Multilateral Fixators and Accessories
Panel Code	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

Predicate Device	510(k) #	Manufacturer
Orthofix TL-HEX True Lok Hexapod System (TL-HEX) V1.3	K143125	Orthofix Srl

<b>Description</b>	<p>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.</p> <p>Components of the system include:</p> <ul style="list-style-type: none"> <li>• Full, 5/8 and 3/8 aluminum Rings</li> <li>• Double Row Footplates</li> <li>• Adjustable struts</li> <li>• Aluminum strut clips (number and direction)</li> <li>• Stainless steel instrumentation such as hex drivers, wrenches, and pliers</li> <li>• Implantable components such as half pins and wires</li> <li>• Web-based software</li> </ul>
--------------------	---

<b>Indications and Intended Use</b>	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. The TL-HEX System is intended for limb lengthening by metaphyseal or epiphyseal distractions, fixation of open and
-------------------------------------	---

	<p>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:</p> <ul style="list-style-type: none"> <li>• Post-traumatic joint contracture which has resulted in loss of range of motion</li> <li>• Fractures and disease which generally may result in joint contractures or loss of range of motion and fractures requiring distraction</li> <li>• Open and closed fracture fixation</li> <li>• Pseudoarthrosis of long bones</li> <li>• Limb lengthening by epiphyseal or metaphyseal distraction</li> <li>• Correction of bony or soft tissue deformities</li> <li>• Correction of bony or soft tissue defects</li> <li>• Joint arthrodesis</li> <li>• Infected fractures or non-unions</li> </ul>
<p><b>Technological Characteristics and Substantial Equivalence</b></p>	<p>Documentation was provided to demonstrate that the Orthofix TL-HEX True Lok Hexapod System (TL-HEX) V1.4 is substantially equivalent to the predicate Orthofix TL-HEX True Lok Hexapod System (TL-HEX) V1.3 in intended use, operating principle, basic design, materials and components.</p>
<p><b>Performance Data</b></p>	<p>The subject device hardware is identical to the predicate device so additional testing of the hardware are not required. It was determined through risk management that no new risks are introduced as a result of the modified indication.</p> <p>Software verification and validation testing was completed in conformance with FDA's guidance document entitled "General Principles of Software Validation; Final Guidance for Industry and FDA Staff." The results of software testing indicate that the software performs as intended. The results demonstrated that the Subject device presents no new worst case for performance testing. The Subject device was therefore found to be substantially equivalent to the predicate.</p> <p>Clinical data was not needed to support the safety and effectiveness of the Subject Device.</p>
<p><b>Conclusion</b></p>	<p>Based on the comparison to predicate device, the Subject Orthofix TL-HEX True Lok Hexapod System (TL_HEX) V1.4 has been shown to be substantially equivalent to its legally marketed predicate device.</p>