February 10, 2023

OrthoPediatrics Corp.
Yan Li
Regulatory Affairs Manager
2850 Frontier Drive
Warsaw, Indiana 46582

Re: K223786
Trade/Device Name: Orthex External Fixation System
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: December 16, 2022
Received: December 19, 2022

Dear Yan Li:

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 -S

Ting Song, 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K223786

Device Name
Orthex External Fixation System

Indications for Use *(Describe)*
The OrthoPediatrics Orthex External Fixation System is intended for external fixation with the following indications:
• Stabilization of Fractures & Osteotomy
• Rear and Mid-foot Foot Arthrodesis
• Adult and Pediatric Leg Lengthening
• Correction of Bone Deformity in Upper & Lower Extremities
The P&C Software is intended to be used as a component of multilateral external fixation system for the indications listed above.

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

I. Submitter

Submission:	Traditional 510(k) Premarket Notification
Applicant:	OrthoPediatrics Corp.
Applicant Address:	2850 Frontier Drive, Warsaw, IN 46582
Establishment Registration Number:	3006460162
Contact:	Yan Li
Contact Phone:	(574) 267-0864
Date Prepared:	February 1, 2023

II. Device

Device Trade Name:	Orthex External Fixation System
Regulation Number:	21 CFR 888.3030
Regulation Name:	Single/Multiple Component Metallic Bone Fixation Appliances and Accessories
Device Classification:	II
Classification Panel:	Orthopedic
Classification Product Code:	KTT, OSN

III. Predicate Device and Reference Device

Substantial equivalence is claimed to the following predicate device:

- **Primary Predicate:** X-Fix Line Additions (K151881, OrthoPediatrics Corp.)

This submission includes the following reference device:

- **Reference Predicate:** Orthofix Truelok Hexapod System (TL-HEX) V2.0 (K170650, Orthofix srl)

Note:

1. In 2015, Vilex in Tennessee, Inc. submitted K151881 for "X-Fix Line Additions" and received the clearance of additional external fixation components and the **Point and Click (P&C) Software** for the Orthex External Fixation System.

2. On June 4, 2019, OrthoPediatrics Corp. ("OrthoPediatrics") purchased all of the issued and outstanding shares of stock of Vilex in Tennessee, Inc. ("Vilex"), and Vilex became a wholly owned subsidiary of OrthoPediatrics Corp. According to the purchase agreement, OrthoPediatrics becomes the manufacturer of the Orthex External Fixation System and the owners of the predicate 510(k) for the system.

IV. Device Description

The OrthoPediatrics Orthex External Fixation System is an external fixator which includes typical components such as rings, partial rings, footplates, monolateral rails, and numerous hardware necessary for the construction of a frame to which tensioned wires and half pins are attached to the bone and to the frame itself. The system has an optional software to assist the user in adjusting the hexapod.

The components included in external fixation systems are made from various types of metal and plastic materials. Half pins and wires are manufactured from implant grade materials and are non-pyrogenic. External fixation components and implants are for single use only and not designed or sold for any use except as indicated.

The web-based Orthex Point and Click (P&C) Software aids the surgeon in the use of the Orthex External Fixation System. The software is optional to use. The Orthex Point and Click (P&C) Software does not control any hardware (such as rings, struts, wires, half pins) directly. The Point and Click (P&C) Software is only compatible with the Orthex External Fixation System. It can be accessed at www.orthex.net. The Pre-Operative planning function of the software aids the surgeon in pre-operative deformity analysis which includes determining where an osteotomy will be made, visualizing corrections, and planning for hexapod construction by positioning rings and calculating the initial strut lengths in preparation for frame application. The Post-Operative planning function of the software aids the surgeon in producing a strut length schedule to achieve the desired correction. The patient or caregiver manually adjusts the struts according to the strut length schedule.

V. Indications for Use

The OrthoPediatrics Orthex External Fixation System is intended for external fixation with the following indications:

- Stabilization of Fractures & Osteotomy
- Rear and Mid-foot Foot Arthrodesis
- Adult and Pediatric Leg Lengthening
- Correction of Bone Deformity in Upper & Lower Extremities

The P&C Software is intended to be used as a component of multilateral external fixation system for the indications listed above.

When the hardware of the Orthex External Fixation System was cleared under K052196, K132820, K163487, the indication of "Rear and Mid-foot Foot Arthrodesis" was cleared, however this indication was removed when the software v1.1 was initially cleared under K151881, as the software at that time did not yet include the foot and ankle modules and icons to support this indication. The subject software now includes foot and ankle module and icons to support this indication. Since the foot and ankle anatomical modules exists in the subject software, the indication of "Rear and Mid-foot Foot Arthrodesis" is added back to the full set of indications for the Orthex External Fixation System. Adding back this indication provides consistency so that the hardware and software of the Orthex External Fixation System have identical intended use and indications for use.

VI. Comparison of Technological Characteristics

The Orthex External Fixation System and the predicate devices share the same intended use, principle of operation, anatomical sites, and many other fundamental technological characteristics.

Updates made to the software since its initial clearance via K151881 include adding the pre-operative planning function, changing the schedule outputs formatting and improving the X-Ray pages' functionality. The safety and effectiveness of all the updates made to the software since its initial clearance have been successfully verified and validated. The software documentation including the verification and validation testing support that the subject software has met applicable design requirements established based on their intended use. Therefore, the updates made to the predicate software cleared via K151881 do not raise new questions of safety or effectiveness.

An evaluation has been done on the hardware of the Orthex External Fixation System to evaluate safety in the MR environment. A magnet was passed over the device ensuring contact is made between the magnet and device. Multiple hardware components exhibit magnetic properties and are supported by the magnet under their own weight. The subject device's labeling was revised to indicate "The Orthex External Fixation System is MR unsafe."

VII. Performance Data

There is no new hardware to be added to the Orthex External Fixation System via this submission. All class II hardware in the Orthex External Fixation System has been cleared in previous 510(k)s. Thus, bench testing or biocompatibility testing on the hardware is not necessary to support the change of MRI safety labeling to "MR unsafe" or to support the safety and effectiveness of the updated software. The Orthex External Fixation System have been evaluated for use in an MR Environment. There are components in the system that contain ferromagnetic materials and thus it is determined that Orthex External Fixation System is MR Unsafe. Successful software verification and validation testing have been conducted to support the safety and effectiveness of the updates made the software since its initial clearance via K151881.

VIII. Conclusion

The information provided above supports that the Orthex External Fixation System is as safe and effective as the predicate device. Information and data provided within the submission support the differences between the subject and predicate devices. Therefore, it is concluded that the Orthex External Fixation System is substantially equivalent to the predicate device.

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