March 7, 2025

OrthoPediatrics Corp.
Jessica Powers
Regulatory Affairs Specialist
2850 Frontier Dr.
Warsaw, Indiana 46582

Re: K243798
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, JDW
Dated: January 10, 2025
Received: January 10, 2025

Dear Jessica Powers:

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.

510(k) Number *(if known)*
K243798

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 (greater than 2 through 21 years of age) 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.

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

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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:	Jessica Powers
Contact Phone:	(574) 268-6379
Date Prepared:	January 10, 2025

II. Device

Device Trade Name:	Orthex External Fixation System
Common Name:	External Fixation System
Device Classification:	II
Classification Panel:	Orthopedic
Regulation Number:	21 CFR 888.3030
	21 CFR 888.3040
Device Classification Name:	Single/multiple component metallic bone fixation appliances and accessories
	Smooth or threaded metallic bone fixation fastener
Classification Product Code:	KTT
	OSN
	JDW

III. Predicate Device and Reference Device

Substantial equivalence is claimed to the following predicate devices:

Primary Predicate Device:

- Orthex External Fixation System (K223786, OrthoPediatrics Corp.)

Secondary Predicate Device:

- Ultima HA Coated Half Pins and Wire (K163487, OrthoPediatrics Corp.)

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 components included in the external fixation system 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 Point and Click (P&C) Software is only compatible with the Orthex External Fixation System. It can be accessed at www.orthex.net. The use of software is optional and is utilized with the bridging and additional necessary hardware elements of the frame.

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 (greater than 2 through 21 years of age) 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.

VI. Comparison of Technological Characteristics

The Orthex External Fixation System is substantially equivalent to the predicate device Orthex External Fixation System (K223786 and K163487) in that these devices have the same intended use, principle of operation, device classification, product code, sterilization, packaging and many other similar fundamental technological characteristics. There are some differences between the predicate and subject devices in terms of materials, sizes and design features. The successful testing data provided in this submission supported that the differences between the subject and predicate devices do not raise different questions for safety and effectiveness.

VII. Performance Data

The biocompatibility assessment and testing for the Orthex External Fixation System were performed in conformance with ISO 10993-1.

Mechanical performance evaluations included self-taping, insertion torque, and torsional strength testing per ASTM F543 and static and dynamic bending based on ASTM F1541.

Hydroxyapatite (HA) Coating performance and characterization evaluations included tension testing of HA coating on titanium substrate per ASTM F1147, characterization of crystallinity and phase purity on HA coating by XRD analysis per ISO 13779-2 and ISO 13779-3, chemical analysis on HA coating per ISO 13779-2, characterization of HA coating molecular constitution by FTIR following FDA Guidance: 510(K) Information Needed for Hydroxyapatite Coated Orthopedic Implants, and evaluation of dissolution rate of HA coating per ASTM F1926/1926M.

Results of the performance testing demonstrate substantially equivalent performance of the subject device as compared to the predicate.

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.