April 8, 2022

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

Re: K220809
Trade/Device Name: Drive Rail 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, JDW
Dated: March 18, 2022
Received: March 21, 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, 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K220809

Device Name
Drive Rail System

Indications for Use *(Describe)*
The Drive Rail System is intended to be used on adult or pediatric patients in the treatment of conditions of the long bones of the arms and legs including limb lengthening, acute or gradual multiplanar correction of long bone deformities, fractures and diseases which generally may result in joint contractures or loss of range of motion, fractures requiring distraction, open or closed fractures, non- unions, and 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.

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3.0 510(k) Summary

I. Submitter

Submission:	Special 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:	March 18, 2022

II. Device

Device Trade Name:	Drive Rail System
Regulation Number:	21 CFR 888.3030
Product Code and Common Name:	KTT: Appliance, Fixation, Nail/Blade/Plate Combination, Multiple Component JDW: Pin, Fixation, Threaded
Device Classification:	II
Classification Panel:	Orthopedic

III. Predicate Device

Substantial equivalence is claimed to the following predicate devices:

Predicate: Drive Rail System, K140822, OrthoPediatrics Corp.

Note: K140822 was submitted by Devise Ortho Inc. in 2014, however, Devise Ortho Inc. was purchased by OrthoPediatrics Corp on April 20, 2021. OrthoPediatrics is the owner of K140822 and the manufacturer of the Drive Rail System.

IV. Device Description

The Drive Rail System is a unilateral external fixation system that consists of various components used in the management of lower extremity bone fractures and reconstructive, as well as corrective, orthopedic surgery. The system consists of 316LVM stainless steel half pins along with frame components including rail segments, pin clamps, distraction/compression

devices and associated accessories made from aluminum and stainless-steel materials. These components should be combined to build a frame which is appropriate for each specific application. All half pins and frame components are single use devices and are provided non-sterile.

The worm gear component in the Drive Rail System is made of 17-4 stainless steel, which is ferromagnetic. Since the worm gear component is magnetic and is within each external rail construct, the Drive Rail System is MR unsafe.

V. Indications for Use

The Drive Rail System is intended to be used on adult or pediatric patients in the treatment of conditions of the long bones of the arms and legs including limb lengthening, acute or gradual multiplanar correction of long bone deformities, fractures and diseases which generally may result in joint contractures or loss of range of motion, fractures requiring distraction, open or closed fractures, non-unions, and infected fractures or non-unions.

VI. Comparison of Technological Characteristics

The OrthoPediatrics Drive Rail System and predicate devices share identical indications for use, device classification, product code. They are used in the same anatomical sites and have the same principle of operation, materials, sterilization, packaging, design and fundamental technological characteristics. The difference between the predicate device and the subject device is that the predicate device labeling states that "The Drive Rail System has not been evaluated for safety and compatibility in the MR environment. It has not been tested for heating, migration, or image artifact in the MR environment.", and the proposed labeling for the subject device is that "The Drive Rail System is MR Unsafe." as the component in the Drive Rail System contains ferromagnetic material.

VII. Performance Data

The purpose of this submission is to obtain clearance to label the Drive Rail System as "The Drive Rail System is MR Unsafe". When the Drive Rail System was cleared under K140822, the system has the labeling "The Drive Rail System has not been evaluated for safety and compatibility in the MR environment. It has not been tested for heating, migration, or image artifact in the MR environment."

According to page 23 and 24 of FDA's guidance "*Testing and Labeling Medical Devices for Safety in the Magnetic Resonance (MR) Environment - Guidance for Industry and Food and Drug Administration Staff*" issued on May 20, 2021. **If the medical device contains ferromagnetic material(s), manufacturers cannot use the labeling of "Safety in MR environment not evaluated"**.

According to page 10 of 36 of the FDA guidance *"The Special 510(k) Program, Guidance for Industry and Food and Drug Administration Staff"* issued on September 13, 2019, when addressing the question of **Are performance data needed to evaluate the change?** It states that "Verification and validation testing, however, may not be necessary to support SE. For example, FDA may receive a 510(k) from a manufacturer requesting clearance to label their device as Magnetic Resonance (MR) Unsafe after previously labeling their device as 'Safety in MR Imaging Not Evaluated.' As discussed in the FDA guidance document Establishing Safety and Compatibility of Passive Implants in the Magnetic Resonance (MR) Environment, **MR Unsafe labeling is based on a scientific rationale and does not involve any performance data.**"

Therefore, OrthoPediatrics Corp reviewed drawings and conducted test to determine of component in the system contains ferromagnetic materials and is magnetic.

VIII. Conclusion

The information provided above supports that the Drive Rail System is as safe and effective as the predicate device. Information provided within the submission support the differences between the subject and predicate devices and support the labeling change. Therefore, it is concluded that the Drive Rail System is substantially equivalent to the predicate devices.

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