September 18, 2024

Response Ortho Solutions LLC
℅ Kevin Walls
Principal Consultant
Regulatory Insight, Inc.
33 Golden Eagle Lane
Littleton, Colorado 80127

Re: K241769
Trade/Device Name: Response Ortho Metaphyseal Hinge Fixator 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
Dated: June 10, 2024
Received: June 20, 2024

Dear Kevin Walls:

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.

Submission Number *(if known)*

K241769

Device Name

Response Ortho Metaphyseal Hinge Fixator System

Indications for Use *(Describe)*

The Response Ortho Metaphyseal Fixation System is indicated for treatment of bone conditions including leg lengthening, osteotomies, arthrodesis, fracture fixation, and other bone conditions amenable to treatment by use of the external fixation.

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.

Response Ortho Metaphyseal Hinge Fixator System 510(k) Summary

Contact Details 21 CFR 807.92(a)(1)

Applicant Name: Response Ortho Solutions LLC

Applicant Address: 1875 W Woolbright Rd Boynton Beach FL 33426 United States

Applicant Contact Telephone:720-254-5756

Applicant Contact: Mr. Şehmuz IŞIN

Applicant Contact Email: sehmuz.isin@responseortho.com

Correspondent Name: Regulatory Insight, Inc.

Correspondent Address: 33 Golden Eagle Lane Littleton CO 80127 United States

Correspondent Contact Telephone: 720-254-5756

Correspondent Contact: Mr. Kevin Walls

Correspondent Contact Email: kevin@reginsight.com

Device Name 21 CFR 807.92(a)(2)

Device Trade Name: Response Ortho Metaphyseal Hinge Fixator System

Common Name: External fixation system

Classification Name: Single/multiple component metallic bone fixation appliances and accessories

Regulation Number: 888.3030

Product Code(s): KTT

Legally Marketed Predicate Devices 21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K001358	EBI XFIX DFS Metaphyseal Correction System	KTT
K201253	Modular Rail System, TAYLOR SPATIAL FRAME External Fixator, JET-X Fixator, ILIZAROV External Fixator, Other External Fixation	KTT

Device Description Summary 21 CFR 807.92(a)(4)

The Response Ortho Metaphyseal Hinge Fixator System is a unilateral fixation device intended for use in the treatment of bone conditions including leg lengthening, osteotomies, arthrodesis, fracture fixation, and other bone conditions amenable to treatment by use of the external fixation modality. The system is designed to provide low profile and comprehensive solution invasively. Implants, reusable instruments, accessories, case&tray are included in the system. Products are non-sterile and implants that exist in the set, are single use. Instruments that are in the system, can be used repeatedly after cleaning and sterilization.

Response Ortho Metaphyseal Hinge Fixator Systems are applied by doctors who, received orthopedic training and have the required technical knowledge, invasive in sterilized surgical conditions.

Intended Use/Indications for Use 21 CFR 807.92(a)(5)

The Response Ortho Metaphyseal Fixation System is indicated for treatment of bone conditions including leg lengthening, osteotomies, arthrodesis, fracture fixation, and other bone conditions amenable to treatment by use of the external fixation.

Indications for Use Comparison 21 CFR 807.92(a)(5)

Since differences in design features will not change the intended use or anatomical site, a new indication will not be created. Differences in the design features given in the "Subject Device Predicate Device Comparison" document do not create a new indication as they will not change the intended use or anatomical region. These design improvements were added to simplify operation and improve the product, and comparison of the devices with mechanical tests is presented.

Technological Comparison 21 CFR 807.92(a)(6)

The subject device has similar technological characteristics as the predicate devices as identified in the attached comparison tables.

Summary of Technological Characteristics 21 CFR 807.92(a)(6)

The product is an External Fixator especially designed for deformity correction with the following features:

- Slim, light and ergonomically fixator-body
- Since tibial plateau dimensions will vary anatomically, Metaphyseal Hinge Fixator; It is designed in 3 different sizes for right and left directions: Small (S), Medium (M) and Large (L).
- Pin placement in anatomical unproblematic areas
- Stable Fixation of the bone fragments with only 4 pins
- Center of rotation at the correct location
- Stable screw fixation with a double cone
- Aid-device for intraoperative placement

Non-Clinical and/or Clinical Tests Summary 21 CFR 807.92(b)

The following non-clinical tests were performed

- Determination and Comparison of Stiffness for Response Ortho Metaphyseal Hinge Fixator and EBI XFIX DFS Metaphyseal Correction System Constructs using Half Pins
- Evaluation of The Response Ortho Metaphyseal Hinge Fixator System and EBI XFIX DFS Metaphyseal Correction System Bridging Element Fatigue
- Evaluation of Function and Strength for Response Ortho Metaphyseal Hinge Fixator Distraction Mechanism under Constant Loading
- Evaluation of Response Ortho Half Pin Performance

- Determination and Comparison of Stiffness for Response Ortho Metaphyseal Hinge Fixator System and EBI XFIX DFS Metaphyseal Correction System Constructs using Half Pins
- Evaluation of Metaphyseal Hinge Fixator and EBI XFIX DFS Metaphyseal Correction System Bridging Element Fatigue
- Evaluation of Function and Strength for Response Ortho Metaphyseal Hinge Fixator Distraction Mechanism under constant loading

There were no clinical tests required for this premarket notification.

Non-Clinical and/or Clinical Tests Conclusions 21 CFR 807.92(b)

The Response Ortho Metaphyseal Hinge Fixator System has been found to be substantially equivalent to the predicate devices with respect to intended use, technological characteristics, and performance.

The information provided within this 510(k) premarket notification demonstrates that the Response Ortho Metaphyseal Hinge Fixator System is as safe and effective as the predicate devices.