November 20, 2025

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

Re: K252625
Trade/Device Name: The Response Ortho Smart Fixator - Hexapod 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: October 22, 2025
Received: October 23, 2025

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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K252625

Please provide the device trade name(s).

The Response Ortho Smart Fixator - Hexapod System

Please provide your Indications for Use below.

INTENDED USE
The Response Ortho Smart Fixator - Hexapod System is intended for use in adult patients and pediatric patients greater than 2 through 21 years of age for the treatment of open and closed fractures, arthrodesis and pseudoarthrosis of long bones, limb lengthening, deformity and angular correction, bony or soft tissue defect correction, and malunions. This is accomplished by construction of an external fixator frame and a computer-assisted planning and correction application. Based on surgeon input of examination and radiographic measurements, the software provides a schedule of adjustments for the fixator frame.

INDICATIONS FOR USE
The Smart Fixator - Hexapod System is indicated for adult patients and pediatric patients greater than 2 through 21 years of age for the following:
• Joint contracture resulting in loss of range of motion.
• Fractures and disease which generally may result in joint contractures or loss of range of motion.
• Fractures requiring distraction.
• Open and closed fracture fixation, including fractures of long bones (intracapsular, intertrochanteric, supracondylar, condylar).
• Correction of bony or soft tissue defects.
• Correction of bony or soft tissue deformities.
• Joint arthrodesis.
• Infected fractures or nonunion.
• Limb lengthening by epiphyseal or metaphyseal distraction.
• Pseudoarthrosis of long bones.

Please select the types of uses (select one or both, as applicable).

- ☒ Prescription Use (Part 21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

510(k) #: K252625

510(k) Summary

Prepared on: 2025-11-19

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Response Ortho Solutions LLC
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Correspondent Contact	Mr. Kevin Walls
Correspondent Contact Email	kevin@reginsight.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	The Response Ortho Smart Fixator - Hexapod System
Common Name	Single/multiple component metallic bone fixation appliances and accessories
Classification Name	Appliance, Fixation, Nail/Blade/Plate Combination, Multiple Component
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
K193368	Smart Correction System	KTT
K221366	Smart Correction System Rings and Compatible HA-Coated Half Pins	KTT
K231461	Smart Correction System (HA Half Pins)	KTT
K223786	Orthex External Fixation System	KTT
K243798	Orthex External Fixation System	KTT

Device Description Summary

21 CFR 807.92(a)(4)

The Response Ortho Medical Smart Fixator - Hexapod System: a multilateral hexapod circular external fixator device used to stabilize and maintain alignment of complicated fractured bones, soft tissues and/or congenital deformity repairs of an extremity. The basic system consists of a minimum of two rings connected by six (6) telescopic struts that are lengthened and shortened independently. The struts' independent motion allows the surgeon to adjust the position of the proximal and distal ring. The system allows for movement in six different axes to correct difficult trauma extremity situations and/or congenital limb deformity correction. The Smart Fixator - Hexapod System capitalizes on the body's natural ability of osteogenesis, guiding the orientation and position of this new bone to the desired corrected location in a steady controlled fashion. In addition to the hardware, the Smart Fixator - Hexapod System has a web-based software treatment planning tool with Radiographic Navigation. The surgeon enters data from direct examination, radiographic images and the fixator parameters into the software. The software is used preoperatively to plan the reconstruction/correction and identify the frame construction. Post operatively, the surgeon enters the X-ray images and the current frame parameters to establish an adjustment schedule for the patient during the healing process.

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

INTENDED USE
The Response Ortho Smart Fixator - Hexapod System is intended for use in adult patients and pediatric patients greater than 2 through 21 years of age for the treatment of open and closed fractures, arthrodesis and pseudoarthrosis of long bones, limb lengthening, deformity and angular correction, bony or soft tissue defect correction, and malunions. This is accomplished by construction of an external fixator frame and a computer-assisted planning and correction application. Based on surgeon input of examination and radiographic measurements, the software provides a schedule of adjustments for the fixator frame.

INDICATIONS FOR USE
The Smart Fixator - Hexapod System is indicated for adult patients and pediatric patients greater than 2 through 21 years of age for the following:
- Joint contracture resulting in loss of range of motion.
- Fractures and disease which generally may result in joint contractures or loss of range of motion.
- Fractures requiring distraction.
- Open and closed fracture fixation, including fractures of long bones (intracapsular, intertrochanteric, supracondylar, condylar).
- Correction of bony or soft tissue defects.
- Correction of bony or soft tissue deformities.
- Joint arthrodesis.
- Infected fractures or nonunion.
- Limb lengthening by epiphyseal or metaphyseal distraction.
- Pseudoarthrosis of long bones.

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

The subject device has the same intended use and indications as the predicate devices.

Technological Comparison 21 CFR 807.92(a)(6)

All systems are hexapod fixator systems. A standard frame consists of two circular rings; one proximal and one distal to the zone of injury. Six telescoping struts. are connected to the distal and proximal ring creating a ring block or bridge for stability during the healing process. The bridge is anchored to the patient's bone with wires and half pins. The implants are secured to the frame by appropriate connectors. The final construct is tightened, and the surgeon will use the software tool to provide the patient a schedule of strut adjustments. The subject and predicate systems have the same overall device design, same types of elements, and elements of similar design.

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

Tests were carried out according to the ASTM F1541-17 standard to observe the mechanical performance of the medical device. The specified predicate device was also tested. Test results of subject and predicate devices were prepared and presented in comparison reports.

Based on the comparison to the predicate devices (K193368, K221366, and K231461), and results from verification and validation testing including mechanical testing, biocompatibility evaluation, sterilization validation, and software verification and validation, the Smart Fixator – Hexapod External Fixation System meets all applicable performance and safety requirements. The results demonstrate that the device performs as intended under normal conditions of use and does not raise different questions of safety or effectiveness. Therefore, the Smart Fixator – Hexapod External Fixation System is considered substantially equivalent to the identified predicate devices.