September 18, 2018

OrthoPediatrics, Corp.
Mr. Mark Fox
Vice President of Regulatory Affairs
2850 Frontier Drive
Warsaw, Indiana 46582

Re: K181390
Trade/Device Name: Response Spine System, Response 5.5/6.0 Spine System, Response 4.5/5.0 Spine System
Regulation Number: 21 CFR 888.3070
Regulation Name: Thoracolumbosacral pedicle screw system
Regulatory Class: Class II
Product Code: NKB, KWP
Dated: August 22, 2018
Received: August 27, 2018

Dear Mr. Fox:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Ronald P. Jean -S

for Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
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)*
K181390

Device Name

Response Spine System, Response 5.5/6.0 Spine System, Response 4.5/5.0 Spine System

Indications for Use *(Describe)*

The Response Spine System (Response 4.5/4.0 & Response 5.5/6.0 Spine Systems) is intended for immobilization and stabilization of the posterior, non-cervical spine in skeletally mature patients as an adjunct to fusion for the following indications: degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, trauma (i.e., fracture or dislocation), spinal stenosis, curvatures (i.e., scoliosis, kyphosis, or lordosis), tumor, pseudoarthrosis, and/or failed previous fusion.

When used for posterior non-cervical pedicle screw fixation in pediatric patients, the Response Spine System implants are indicated as an adjunct to fusion to treat adolescent idiopathic scoliosis. The Response Spine System is intended to be used with autograft and/or allograft. Pediatric pedicle screw fixation is limited to a posterior approach.

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

In accordance with 21 CFR §807.92 and the Safe Medical Devices Act of 1990, the following information is provided for the OrthoPediatrics Response Spine System 510(k) premarket notification. The submission was prepared in accordance with the FDA guidance document, 'Format for Traditional and Abbreviated 510(k)s', issued on August 12, 2005.

Sponsor:	OrthoPediatrics, Corp. 2850 Frontier Drive Warsaw, IN 46582 Establishment Registration Number: 3006460162
Contact Person:	Mark Fox V.P. Regulatory Affairs Phone: (574) 267-6379 Fax: (574) 269-3692
Date:	May 25, 2018
Subject Device:	**Trade Name**: Response Spine System Response 5.5/6.0 Spine System Response 4.5/5.0 Spine System **Common Name**: Pedicle Screw Spinal System **Classification Name**: **NKB** 21 CFR 888.3070: Thoracolumbosacral Pedicle Screw System **KWP** 21 CFR 888.3050: Spinal Interlaminal Fixation Orthosis

Legally marketed devices to which substantial equivalence is claimed:

- Response 5.5/6.0 Spine System (K150600)

Device Description:

The **Response Spine System** is a pedical screw spinal implant system consisting of longitudinal members (rods), anchors (hooks and screws), interconnection components (rod-to-rod and anchor-to-rod connectors) and fasteners in a variety of sizes to accommodate differing anatomic requirements.

Indications for Use:
The **Response Spine System** (Response 5.5/6.0 and Response 4.5/5.0 Spine Systems) is intended for immobilization and stabilization of the posterior, non-cervical spine in skeletally mature patients as an adjunct to fusion for the following indications: degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, trauma (i.e., facture or dislocation), spinal stenosis, curvatures (i.e., scoliosis, kyphosis, or lordosis), tumor, pseudoarthrosis, and/or failed previous fusion.

When used for posterior non-cervical pedicle screw fixation in pediatric patients, the Response Spine System implants are indicated as an adjunct to fusion to treat adolescent idiopathic scoliosis. The Response Spine System is intended to be used with autograft and/or allograft. Pediatric pedicle screw fixation is limited to a posterior approach.

Summary of Technological Characteristics:
The intended use, indications for use, materials, sterilization methods, device design, and principle of operation of the subject device are the same as the predicate device. Differences in device sizes do not introduce any new risks of safety and efficacy. The **Response Spine System** including the 4.5/5.0 size offerings is substantially equivalent to the Response 5.5/6.0 Spine System for the primary intended use as an adjunct to fusion as described in the device labeling.

Summary of Performance Data (Mechanical Testing - Bench):

Static and dynamic compression bending, and static torsion tests were used to characterize the mechanical properties of the worst case line extension Response 4.5/5.0 Spinal System pedicle screw constructs.
The static results show the Response 4.5/5.0 Spinal System has static yield and stiffness, and dynamic compression bending runout properties comparable to cleared, predicate systems. Overall, the results show the Response 4.5/5.0 Spinal System to have properties comparable to or better than other commercially available, adult-indicated posterior pedicle screw devices.

Clinical Tests:
Clinical data was not required to establish substantial equivalence between the subject device and the predicate device.

Substantial Equivalence Conclusion
Based on identical design technology, materials, intended use, and indications for use, the subject device is similar to the predicate device and does not introduce any new risks of safety or efficacy. Therefore, Orthopediatrics, Corp concludes that the **Response Spine System** is substantially equivalent to the predicate device.