March 24, 2020

OrthoPediatrics, Corp.
Ms. Jackie Jaskula
Regulatory Affairs Manager
2850 Frontier Drive
Warsaw, Indiana 46582

Re: K193100
Trade/Device Name: RESPONSE™ Spine System, RESPONSE™ 4.5/5.0 Spine System, RESPONSE™ 5.5/6.0 Spine System
Regulation Number: 21 CFR 888.3070
Regulation Name: Thoracolumbosacral Pedicle Screw System
Regulatory Class: Class II
Product Code: NKB, KWP
Dated: February 28, 2020
Received: March 2, 2020

Dear Ms. Jaskula:

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,

Colin O'Neill, M.B.E.
Acting Assistant Director
DHT6B: Division of Spinal 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)*
K193100

Device Name
RESPONSE™ Spine System
RESPONSE™ 4.5/5.0 Spine System
RESPONSE™ 5.5/6.0 Spine System

Indications for Use *(Describe)*

The RESPONSE 4.5/5.0 and 5.5/6.0 Spine Systems are 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, pseudarthrosis, and/or failed previous fusion.

When used for posterior non-cervical pedicle screw fixation in pediatric patients, the Response 4.5/5.0 and 5.5/6.0 Spine System implants are indicated as an adjunct to fusion to treat adolescent idiopathic scoliosis, neuromuscular scoliosis, and congenital scoliosis. The Response 4.5/5.0 and 5.5/6.0 Spine Systems are 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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3.0 510(k) Summary

I. Submitter

OrthoPediatrics, Corp
2850 Frontier Drive
Warsaw, IN 46582
Establishment Registration Number: 3006460162

Contact Person: Jackie Jaskula, Regulatory Affairs Manager
Phone: 574-267-0817
Date Prepared: November 5, 2019

II. Device

Device Proprietary Name:	RESPONSE™ Spine System RESPONSE™ 4.5/5.0 Spine System RESPONSE™ 5.5/6.0 Spine System
Common or Usual Name:	Pedicle Screw Spinal System
Classification Name:	Thoracolumbosacral Pedicle Screw System Spinal Interlamination Fixation Orthosis
Regulation Number:	21 CFR 888.3070 21 CFR 888.3050
Product Code:	NKB, KWP
Device Classification	II

III. Predicate Device

Substantial equivalence is claimed to the following devices:

- Primary Predicate:
  - Response Spine System (Response 5.5/6.0 Spine System, Response 4.5/5.0 Spine System), K181390, OrthoPediatrics, Corp.
- Additional Predicates:
  - CD HORIZON® Spinal System, K141494, Medtronic Sofamor Danek USA, Incorporated
  - Response 5.5/6.0 Spine System, K150600, OrthoPediatrics, Corp.

IV. Device Description

The RESPONSE 4.5/5.0 Spine System and RESPONSE 5.5/6.0 Spine System (herein referred to as the RESPONSE Spine Systems) are pedicle screw spinal implant systems 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. All implant components are manufactured from titanium alloy (6Al-4V-ELI; ASTM F-136), commercially pure titanium (ASTM F67), and cobalt-chromium-molybdenum alloy (ASTM F-1537). All system components and instruments are provided non-sterile.

The longitudinal members (rods) are provided in straight and pre-bent configurations. The anchors include a variety of hooks and pedicle screws. The interconnection components include rod-to-rod and anchor-to-rod connectors. The fasteners include set screws for all the pedicle screws, hooks and connectors. The system is implanted using general (Class I, 510(k) exempt) and specific (Class II) surgical instruments.

This submission adds additional rods, pedicle screws, anchor-to-rod connectors, and Class II instruments to the RESPONSE Spine Systems.

V. Indications for Use

The RESPONSE 4.5/5.0 and 5.5/6.0 Spine Systems are 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, pseudarthrosis, and/or failed previous fusion.

When used for posterior non-cervical pedicle screw fixation in pediatric patients, the Response 4.5/5.0 and 5.5/6.0 Spine System implants are indicated as an adjunct to fusion to treat adolescent idiopathic scoliosis, neuromuscular scoliosis, and congenital scoliosis. The Response 4.5/5.0 and 5.5/6.0 Spine Systems are intended to be used with autograft and/or allograft. Pediatric pedicle screw fixation is limited to a posterior approach.

VI. Comparison of Technological Characteristics

The RESPONSE Spine Systems and predicate implants and instruments are used to correct spinal deformities in skeletally mature patients. The construct provides immobilization and stabilization of spinal segments as an adjunct to fusion of the non-cervical spine in pediatric patients. The construct which is implanted into the patient consists of rods, hooks, and connectors.

The RESPONSE Spine Systems and the predicate devices share the same materials of construction, body contact and duration of contact, principle of operation, and similar design features for implants and instruments, and component types.

The RESPONSE Spine Systems have the same intended use as the primary predicate device when used for posterior, non-cervical immobilization and stabilization in skeletally mature patients. This submission expands the indications for the RESPONSE Spine Systems to include neuromuscular and congenital scoliosis in pediatric patients as in the primary predicate indications.

Components introduced in this submission include screws and rods within the existing validated range as previously cleared RESPONSE Spine System components, anchor-to-rod connectors and instruments with the same mating geometries and materials as existing system components. These components are similar to devices in the previously cleared RESPONSE Spine Systems and the primary predicate. Additionally, the drivers subject to this submission introduce the use of power for provisional set screw tightening, similar to other drivers in the predicate devices.

The subject and predicate device systems contain the identical components with the exception of new implants and instruments subject to this submission. These technological differences do not raise different questions of safety and effectiveness and are addressed by the testing provided within the submission.

VII. Performance Data

The following performance data were provided in support of the substantial equivalence determination:

- dynamic compression bend testing per ASTM 1717-15;
- axial grip testing per ASTM 1798-13;
- static compression bend testing per ASTM 1717-15;
- mechanical testing specific to reducer; and
- user validation studies.

Information submitted under K181390 and K150600 were leveraged to support the following:

- sterilization;
- biocompatibility per ISO 10993-1; and
- dynamic compression bend testing per ASTM 1717.

VIII. Conclusion

The information provided above supports that the RESPONSE Spine Systems are as safe and effective as the predicate devices. Information and data provided within the submission support the differences between the subject and predicate devices. Therefore, it is concluded that the Response Spine Systems are substantially equivalent to the predicate devices.