OrthoPediatrics Corp.
Jennifer Gregory
2850 Frontier Drive
Warsaw, Indiana 46582

March 23, 2023

Re: K222105
Trade/Device Name: RESPONSE 5.5/6.0 Cannulated Screw System
Regulation Number: 21 CFR 888.3070
Regulation Name: Thoracolumbosacral Pedicle Screw System
Regulatory Class: Class II
Product Code: NKB, KWP
Dated: March 9, 2023
Received: March 10, 2023

Dear Jennifer Gregory:

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,

Eileen Cadel -S
Digitally signed by Eileen Cadel -S
Date: 2023.03.23 10:04:20 -04'00'

for

Colin O'Neill, M.B.E.
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K222105

Device Name
RESPONSE 5.5/6.0 Cannulated Screw System

Indications for Use *(Describe)*

• The RESPONSE 4.5/5.0 and 5.5/6.0 Spine Systems and the RESPONSE 5.5/6.0 Cannulated Screw System 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 dicogenic 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 and the RESPONSE 5.5/6.0 Cannulated Screw 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 and the RESPONSE 5.5/6.0 Cannulated Screw System 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.

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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
Submitter:	Natalie Heck
Submitter Phone:	(574) 268-6379
Contact:	Jennifer Gregory
Contact Phone:	574-267-0880
Date Prepared:	March 21, 2023

II. Device

Device Trade Name:	RESPONSE 5.5/6.0 Cannulated Screw System
Regulation Number:	21 CFR 888.3070, 21 CFR 888.3050
Product Code and Common Name:	NKB Thoracolumbosacral Pedicle Screw System KWP Appliance, Fixation, Spinal Interlaminal
Device Classification:	II
Classification Panel:	Orthopedic

III. Predicate Device

Substantial equivalence is claimed to the following predicate devices:

Primary Predicate: RESPONSE 5.5/6.0 Spine System, K193100, OrthoPediatrics Corp.

IV. Submission Purpose: The addition of cannulated screws and associated instruments to the RESPONSE 5.5/6.0 Spine System

V. Device Description

The RESPONSE 5.5/6.0 Cannulated Screw System is a cannulated screw spinal implant system consisting of anchors (screws) that attach to the longitudinal members (rods) and interconnection components (connectors) previously cleared in the RESPONSE 5.5/6.0 Spine System see K193100.

Pedicle screws are placed in the spine that attach to rods that allow immobilization and stabilization of the spine. The RESPONSE 5.5/6.0 Cannulated Screws are cannulated screws that are passed over a guidewire to achieve insertion. The RESPONSE 5.5/6.0 Cannulated Screws are available in a 6mm to 9mm diameter range by 40mm to 100mm lengths.
All implant components are manufactured from titanium alloy, cobalt chrome, and commercially pure titanium. See table below for associated material standards:

Material	Applicable Standard
Implants	N/A
Ti-6Al-4V	ASTM F136
Co28Cr6Mo	ASTM F1537
CP Titanium	ASMT F67

All components are supplied non-sterile.

The screws, which have a Ø1.750 mm cannulation, are available in the following diameters and lengths:
Ø6.0 - 40-80mm
Ø6.5 - 40-90mm
Ø7.0 - 40-100mm
Ø8.0 - 40-100mm
Ø9.0 - 40-100mm

All screws are double lead with a 2.750 mm thread pitch which is identical to the predicate screws.

For the subject screws, the minor diameter, neck diameter and thread runout length were increased and the hexalobe feature and root radius were modified from the predicate pedicle screw design to accommodate the cannulation.

The subject drivers are cannulated with features to interface with the screw hexalobe.

VI. Intended Use

The RESPONSE 5.5/6.0 Cannulated Screws are intended to be used for immobilization and stabilization of the posterior, non-cervical spine in skeletally mature patients as an adjunct to fusion and as an adjunct to fusion to treat scoliosis in pediatric patients in combination with the RESPONSE 5.5/6.0 Spine System. Pediatric cannulated spine screw fixation is limited to a posterior approach.

Cannulated pedicle screws are intended to be used in the thoracolumbosacral spine in skeletally mature and pediatric patients; as such, they are provided in a 6mm to 9mm diameter range.

VII. Indications for Use

The RESPONSE 4.5/5.0 and 5.5/6.0 Spine Systems and the Response 5.5/6.0 Cannulated Screw System 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 and the Response 5.5/6.0 Cannulated Screw 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 and the Response 5.5/6.0 Cannulated Screw System are intended to be used with autograft and/or allograft. Pediatric pedicle screw fixation is limited to a posterior approach.

VIII. Comparison of Technological Characteristics

The RESPONSE 5.5/6.0 Cannulated Screws and predicate implant and instruments are used to correct spinal deformities in skeletally mature and pediatric patients. The construct provides immobilization and stabilization of spinal segments as an adjunct to fusion of the non-cervical spine. The construct, which is implanted into the patient, consists of rods, anchors (hooks and screws), and connectors.

The RESPONSE 5.5/6.0 Cannulated Screws and the predicate devices share the same materials of construction, body contact and duration of contact, principle of operation, and similar design features for implant and instruments, and component types.

The RESPONSE 5.5/6.0 Cannulated Screws have the same intended use as the predicate device.

Components introduced in this submission include screws that fall within the length and diameter combinations of the previously cleared RESPONSE Spine System components and instruments with the same mating geometries and materials as existing system components. With the exception of the cannulation, these components are similar to devices in the previously cleared RESPONSE Spine Systems.

These technological differences do not raise different questions of safety and effectiveness and are addressed by the testing provided within the submission.

IX. Performance Data

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

- dynamic compression bend testing per ASTM F1717-21,
- static compression bend testing per ASTM F1717-21,
- static and dynamic flexion/extension testing per ASTM F1798-21,
- screw pullout strength via ASTM F543-17,
- user validation studies,
- functional relationship analysis,
- MR compatibility per ASTM F2052-21, ASTM F2119-07, ASTM F2182-19 and ASTM F2213-17.

Information submitted under K193100 was leveraged to support the following:

- axial and rotational grip per ASTM F1798-21,
- sterilization per AAMI ST79:17,
- biocompatibility per ISO 10993-1.

X. Conclusion

The information supplied above supports that the RESPONSE 5.5/6.0 Cannulated Screw System is equivalent to the predicate device. Information provided within the submission support the differences between the subject and predicate devices. Therefore, it is concluded that the RESPONSE 5.5/6.0 Cannulated Screw System is substantially equivalent to the predicate device.