



Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

May 22, 2015

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

Re: K150600
Trade/Device Name: Response 5.5/6.0 Spine System
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle screw spinal system
Regulatory Class: Class III
Product Code: NKB, OSH, KWP, MNH, MNI
Dated: May 8, 2015
Received: May 11, 2015

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. 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); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

Lori A. Wiggins -S

for

Mark N. Melkerson

Director

Division of Orthopedic Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K150600

Device Name

Response 5.5/6.0 Spine System

Indications for Use (Describe)

The Response 5.5/6.0 Spine System 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, pseudarthrosis, and/or failed previous fusion.

When used for posterior non-cervical pedicle screw fixation in pediatric patients, the Response 5.5/6.0 Spine System implants are indicated as an adjunct to fusion to treat adolescent idiopathic scoliosis. The Response 5.5/6.0 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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRASStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

OrthoPediatrics Corp.
Response 5.5/6.0 Spine System

510(K) Summary

I.	Submitter	OrthoPediatrics Corp. 2850 Frontier Drive Warsaw, IN 46582 (574) 268-6379
	Contact	Mark Fox Vice President, Regulatory Affairs
	Date Prepared	March 6, 2015
II.	Device	
	Name of Device	Response 5.5/6.0 Spine System
	Classification Name	Pedicle Screw Spinal System (bone screws, rods, & hooks) adolescent idiopathic scoliosis, Spinal Interlaminar Fixation Orthosis, Orthosis spondylolisthesis spinal fixation, Orthosis, Spinal pedicle fixation, Orthosis, spinal pedicle fixation, for degenerative disc disease and Pedicle Screw Spinal System (21 CFR 888.3070 and 888.3050)
	Classification	Class III; 21 CFR 888.3070 and 21 CFR 888.3050
	Product Codes	NKB, OSH, MNH, MNI, KWP
III.	Predicates	K130655 – OrthoPediatrics Response Spine – (PRIMARY) K091445 – Medtronic CD Horizon Spine System K120291 – OrthoPediatrics OP Spine System
		None of the above predicates have been subject to a design-related recall. No reference device was used in this submission.
	Product Description	The Response 5.5/6.0 Spine System consists 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. No accessories are offered with the system.

IV. Indications For Use The Response 5.5/6.0 Spine System 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, pseudarthrosis, and/or failed previous fusion.

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

V. Comparison of Technological Characteristics

The fundamental scientific principles and technological characteristics, including the intended use, material, general design, and sizes of the device are the same as, or similar to, the predicate devices.

This subject system is an expansion of the previously cleared predicate “Response Spine System” (K130655). At a high level, the subject and predicate devices are based on the following same technological elements:

- Implanted into the patient
- Used with rods, hooks, cross-links, and other instrumentation to build a construct
- The subject devices are intended to help provide immobilization and stabilization of spinal segments as an adjunct to fusion of the thoracic, lumbar, and /or sacral spine

VI. Performance Data

The following performance data are provided in support of the substantial equivalence determination.

Mechanical Testing

In accordance with, Guidance for Industry and FDA Staff - Spinal System 510(k)'s, OrthoPediatrics Corp. has evaluated the subject devices to demonstrate substantial equivalence to the predicate devices.

Design verification testing was completed in accordance with ASTM F1717 - Standard Test Methods for Spinal Implant Constructs in a Vertebrectomy Model, and ASTM F1798 – “Standard Guide to Evaluating the Static and Fatigue Properties of Interconnection Mechanisms and Subassemblies Used in Spinal Arthrodesis Implants. The tests completed were:

- - Axial Grip
- - Axial Torsion
- - Flexion Extension Static Testing
- - Flexion Extension Fatigue
- - Construct Static Compression Bending
- - Construct Static Torsion
- - Construct Compression Bending Fatigue

The subject devices met the pre-determined acceptance criteria for all tests.

Biocompatibility

Response 5.5/6.0 Spine System implants are comprised of the same medical grade metals (i.e., Titanium Alloy (Ti-6Al-4V-ELI) per ASTM F136, commercially pure titanium (ASTM F67), and CoCr (ASTM F1537-08)) and have the same type of body contact as other permanently implantable, (>30 days) contact duration, commercially available spinal system components. Response 5.5/6.0 Spine System instruments are comprised of the same material (medical grade stainless Steel) as other commercially available instruments and have patient contact for a transient duration (limited (< 24 hours) contact). These materials have well- characterized levels of biological response and a long history of successful clinical application in implantable and transient use with spinal systems in humans. Furthermore, these materials are identical to the predicate systems, Response Spine System (K130655), OP Spine System (K120291), CD Horizon Spine System (K091445) in formulation, processing, and sterilization and no other chemicals have been added. Biocompatibility met per Flow Chart for the Selection of Toxicity Tests for 510(K)s per FDA Guidance #G95-1 "Use of International Standard ISO-10993, "Biological Evaluation of Medical Devices Part 1: Evaluation and Testing", May 1, 1995. Therefore, biocompatibility testing is not required.

VII. Conclusions

A risk analysis was completed and design verification testing was completed in accordance with ASTM F1717 and ASTM F1798. Based on the test results and additional supporting information provided in this pre-market notification, the subject devices demonstrated substantial equivalence to the legally marketed predicate devices.