DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

August 11, 2016

OrthoPediatrics Corp.
Mr. Mark Fox
Vice President, Regulatory Affairs
2850 Frontier Drive
Warsaw, Indiana 46538

Re: K161267
Trade/Device Name: Response BandLoc Spinal Fixation
Regulation Number: 21 CFR 888.3010
Regulation Name: Bone fixation cerclage
Regulatory Class: Class II
Product Code: OWI
Dated: July 19, 2016
Received: July 20, 2016

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 Parts 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" (21CFR 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,

Vincent J. Devlin -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 Statement

510(K) Number (if known): K161267

Device Name: Response BandLoc Spinal Fixation

Indications for Use:

The RESPONSE BandLoc Spinal Fixation is a temporary implant for use in orthopedic surgery. The system is intended to provide temporary stabilization as a bone anchor during the development of solid bony fusion and aid in the repair of bone fractures. The indications for use include the following applications:

- Spinal trauma surgery, used in sublaminar or facet wiring techniques;
- Spinal reconstructive surgery, incorporated into constructs for the purpose of correction of spinal deformities such as idiopathic and neuromuscular scoliosis in patients 8 years of age and older, adult scoliosis, kyphosis, and spondylolisthesis;
- Spinal degenerative surgery, as an adjunct to spinal fusions.

- The RESPONSE BandLoc Spinal Fixation may also be used in conjunction with other medical implants made of titanium alloy or CoCr alloy whenever "wiring" may help secure the attachment of other implants.

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

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

OrthoPediatrics Corp.
Response BandLoc Spinal Fixation

510(K) Summary

I.	**Submitter**	OrthoPediatrics Corp. 2850 Frontier Drive Warsaw, IN 46538 (574) 268-6379
	Contact	Mark Fox Vice President, Regulatory Affairs
	Date Prepared	August 3, 2016
II.	**Device**	
	Name of Device	Response BandLoc Spinal Fixation
	Classification Name	Bone Fixation, Cerclage
	Classification	Class II; 21 CFR 888.3010
	Product Codes	OWI
III.	**Predicates**	K110348 – Zimmer Universal Clamp Spinal Fixation (PRIMARY)
		K060009 – Abbott (Zimmer) Spine Universal Clamp

IV. Product Description

The *Response BandLoc Spinal Fixation* consists of a woven band, band clip, metal insert, tulip head and set screw. The metal insert, band, band clip and tulip head are assembled at the manufacturer and provided as a one piece assembly to the user. This tulip head/band assembly and the set screw are packaged in the same box but in separate peal packs. The tulip head assembly mates with a spine system rod and the set screw is tightened in the tulip head assembly securing it to the rod. Combinations of 5.5 and 6.0 diameter rods offered in titanium alloy, and/or cobalt chromium can be utilized.

All implants are made from implantable grade materials and provided sterile and are single use only; the implants should not be re-used or re-sterilized under any circumstances.

No accessories are offered with the system.

V. Indications For Use

The RESPONSE BandLoc Spinal Fixation is a temporary implant for use in orthopedic surgery. The system is intended to provide temporary stabilization as a bone anchor during the development of solid bony fusion and aid in the repair of bone fractures. The indications for use include the following applications:

- Spinal trauma surgery, used in sublaminar or facet wiring techniques;
- Spinal reconstructive surgery, incorporated into constructs for the purpose of correction of spinal deformities such as idiopathic and neuromuscular scoliosis in patients 8 years of age and older, adult scoliosis, kyphosis, and spondylolisthesis;
- Spinal degenerative surgery, as an adjunct to spinal fusions.
- The RESPONSE BandLoc Spinal Fixation may also be used in conjunction with other medical implants made of titanium alloy or CoCr alloy whenever "wiring" may help secure the attachment of other implants.

VI. 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.

The subject and predicate devices are based on the following same technological elements:

- Implanted into the patient
- Used with rods and other instrumentation to build a construct
- Identical materials
- Intended to provide temporary stabilization as a bone anchor during the development of solid bony fusion and aid in the repair of bone fractures

VII. 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
- - Static Tension
- - Construct Compression Fatigue

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

Biocompatibility

The RESPONSE BandLoc Spinal Fixation implants are comprised of medical grade metals (i.e. Titanium Alloy (Ti-6A1-4V-ELI) per ASTM F136, and Polyethylene terephtalate thread (PET) and have the same type of body contact as other permanently implantable, (>30 days) contact duration, commercially available spinal system components.
RESPONSE BandLoc Spinal Fixation implants have been tested via bacterial endotoxin test (BET) also known as the Limulus amebocyte lysate (LAL) test, and meet established endotoxin limits per ANSI/AAMI ST72:2011.
RESPONSE BandLoc Spinal Fixation 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. Biocompatibility met per Flow Chart for the Selection of Toxicity Tests for 510(K)s per FDA Guidance #G95-1. Biological testing per IS0-10993, "Biological Evaluation of Medical Devices" Parts 1, 3, 5, 6, 10, 11, and 12.

VIII. 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.