March 16, 2020

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

Re: K200097
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: January 15, 2020
Received: January 16, 2020

Dear Jackie 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,

for

Ronald P. Jean, Ph.D.
Director (Acting)
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)*
K200097

Device Name
Response BandLoc Spinal Fixation

Indications for Use *(Describe)*
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.

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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5.0 510(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 BandLoc Spinal Fixation 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 September 13, 2019.

Sponsor:	OrthoPediatrics, Corp 2850 Frontier Drive Warsaw, IN 46582
Establishment Registration Number:	3006460162
Contact Person:	Jackie Jaskula Regulatory Affairs Manager Phone: (574) 267-0817
Date:	March 13, 2020 (revised)
Subject Device/ Trade Name:	Response BandLoc Spinal Fixation
Common Name:	Bone Fixation Cerclage, Sublaminar
Regulation Name:	Bone Fixation Cerclage
Product Code:	OWI
Regulation Number:	21 CFR 888.3010

Legally marketed primary predicate device to which substantial equivalence is claimed:

- Response BandLoc Spinal Fixation (K161267)

Product Description

The RESPONSE BandLoc Spinal Fixation implant consists of a titanium alloy tulip head clamp attached to a polyester band and includes a set screw for affixing the clamp to a rod used for spinal fusion. The polyester band is available in two configurations—single and double (DUO) band. Both band configurations include a tip portion with an internal titanium insert enclosed in the band to enable the user to more easily pass the tip through the spinal anatomy. The final

implanted devices are identical. Combinations of 5.5 and 6.0 diameter rods offered in titanium alloy, and/or cobalt chromium alloy 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.

This submission adds an additional implant configuration to the system, describes a modification to a system-specific (Class II) instrument, and adds MR conditions to the labeling.

The system is implanted using general (Class I, 510(k) exempt) and system-specific (Class II) instruments.

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.

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 primary predicate devices.

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

- Intended use
- Identical materials
- Identical sterilization methods
- Identical principle of operation
- Device design
- Duration and extent of tissue contact

The metallic components of the subject BandLoc implants are equivalent to the tulip heads in the reference device Response Spine System pedicle screws based on device design, material and material mass, anatomic location of the implant, and principle of operation. The MR compatibility of the Response Spine System pedicle screws was established under K181390.

Performance Data

Mechanical Testing

A risk analysis of the BandLoc DUO line extension was completed in accordance with design control procedures. The risk analysis demonstrated that the subject BandLoc Spinal Fixation does not introduce new issues of safety or effectiveness. The final fusion constructs created using devices in this submission are identical to those in the previous submission K161267. Therefore, mechanical testing data is leveraged from the previous submission K161267 to support the following:

- Mechanical performance of the fusion construct (ASTM F1717) static and dynamic compression testing of a spine construct including pedicle screws, rods, and the BandLoc implant.
- Corrosion susceptibility (ASTM F2129) of the tulip head portion of the implant

OrthoPediatrics performed a tensile strength test by an internal method to demonstrate the BandLoc DUO assembly can withstand the anticipated loads during passage through the sublaminar space. The subject device met the pre-determined acceptance criteria for all tests. Refer to the summary table below.

The BandLoc Tensioner modification was verified through life cycle testing to simulate worst case use. The modified instrument met pre-determined acceptance criteria.

Electromagnetic Compatibility

In non-clinical testing the OrthoPediatrics BandLoc implants have been determined to be MR-Conditional in accordance with the following standards:

ASTM F2052 Standard Test Method for Measurement of Magnetically Induced Displacement Force on Medical Devices in the Magnetic Resonance Environment

ASTM F2213 Standard Test Method for Measurement of Magnetically Induced Torque on Medical Devices in the Magnetic Resonance Environment

ASTM F2182 Standard Test Method for Measurement of Radio Frequency Induced Heating on or Near Passive Implants During Magnetic Resonance Imaging

ASTM F2119 Standard Test Method for Evaluation of MR Image Artifacts from Passive Implants

Biocompatibility

The subject Response BandLoc Spinal Fixation implants and instruments in their final form are identical to the implants and instruments cleared under K161267 with regards to materials of construction, color additives, sterilization, and geometry and no other chemicals have been added (e.g., plasticizers, fillers, additives, cleaning agents, or mold release agents) in the manufacturing processes which may alter the biocompatibility profile of the devices in comparison with the primary predicate devices. Information submitted under K161267 was leveraged to support biocompatibility per ISO 10993-1.

Conclusions

Non-clinical tests provided in this Traditional 510(k) establish the conditional safety and compatibility of the passive implants in a magnetic resonance (MR) environment. Based on the technology, materials, intended use, indications for use, test results and additional supporting information provided in this pre-market notification, the subject device demonstrates substantial equivalence to the legally marketed primary predicate device.