October 29, 2019

Osseus Fusion Systems
% J.D.Webb
Official Correspondent
The OrthoMedix Group, Inc.
4313 W. 3800 S.
West Haven, Utah 84401

Re: K192121
Trade/Device Name: Black Diamond Pedicle Screw System
Regulation Number: 21 CFR 888.3070
Regulation Name: Thoracolumbosacral Pedicle Screw System
Regulatory Class: Class II
Product Code: NKB
Dated: July 31, 2019
Received: August 6, 2019

Dear Mr. Webb:

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 Jean, Ph.D.
Acting 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)*

K192121

Device Name

Black Diamond Pedicle Screw System

Indications for Use *(Describe)*

The Black Diamond Pedicle Screw System, with or without MIS instrumentation, is intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of thoracic, lumbar, and sacral spine: degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies), degenerative spondylolisthesis with objective evidence of neurological impairment, fracture, dislocation, deformities or curvatures (i.e. scoliosis, kyphosis, and/or lordosis), spinal tumor, pseudarthrosis and failed previous fusion.

When used for posterior, non-cervical, pedicle screw fixation in pediatric patients, the Black Diamond Pedicle Screw System implants are indicated as an adjunct to fusion to treat progressive spinal deformities (i.e., scoliosis, kyphosis, or lordosis) including idiopathic scoliosis, neuromuscular scoliosis, and congenital scoliosis. Additionally, the Black Diamond Pedicle Screw System is intended to treat pediatric patients diagnosed with: spondylolisthesis/spondylolysis, fracture caused by tumor and/or trauma, pseudarthrosis, and/or failed previous fusion. This 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.

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K192121
510(k) Summary: Black Diamond Pedicle Screw System

In accordance with 21 CFR 807.92 of the Federal Code of Regulations

Date Prepared	July 31, 2019
Submitted By	Osseus Fusion Systems, LLC 2703 W. Mockingbird Ln., Ste. #102 Dallas, TX 75204
Primary Contact	J.D. Webb 4313 W. 3800 S. West Haven, UT 84401 512-590-5810 Tele e-mail: jdwebb@orthomedix.net
Trade Name	Black Diamond Pedicle Screw System
Common Name	pedicle screw system
Classification Name	Thoracolumbosacral Pedicle Screw System Pedicle Screw Spinal System, Adolescent Idiopathic Scoliosis
Class	II
Product Code	NKB
CFR Section	21 CFR section 888.3070
Device Panel	Orthopedic
Primary Predicate Device	INERTIA Pedicle Screw System, NEXXT Spine (K090984/ K101278/ K132412/ K153453)
Secondary Predicate Devices	Black Diamond Pedicle Screw System, Osseus Fusion Systems (K131810) Vitality® Spinal Fixation System, Zimmer Spine, Inc. (K150896 / K1719007) Xia® 3 Spinal System, Stryker Spine (K091291 / K113666 / K142381) Savannah-T Dual Fix, Amendia (K132925)
Reference Predicate Devices	Synergy VLS – open, Cross Medical Products (K940631 / K950099) Moss Miami SS, DePuy Spine (K950697) Rogozinski, Smith & Nephew Richards (K954696)
Device Description	The Black Diamond Pedicle Screw System is a top loading, multiple component, posterior spinal fixation system which consists of pedicle screws, rods, and cross links. All the components are available in a variety of sizes to match more closely the patient's anatomy
Materials	Ti-6Al-4V per ASTM F136 CoCr per ASTM F1537
Intended Use	Black Diamond Pedicle Screw System is intended to provide immobilization and stabilization of spinal segments until fusion is accomplished

Substantial Equivalence Claimed to Predicate Devices	The Black Diamond Pedicle Screw System is equivalent to the predicate devices in terms of intended use, design, materials used, mechanical safety and performances.
Indications for Use	The Black Diamond Pedicle Screw System, with or without MIS instrumentation, is intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of thoracic, lumbar, and sacral spine: degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies), degenerative spondylolisthesis with objective evidence of neurological impairment, fracture, dislocation, deformities or curvatures (i.e. scoliosis, kyphosis, and/or lordosis), spinal tumor, pseudarthrosis and failed previous fusion. When used for posterior, non-cervical, pedicle screw fixation in pediatric patients, the Black Diamond Pedicle Screw System implants are indicated as an adjunct to fusion to treat progressive spinal deformities (i.e., scoliosis, kyphosis, or lordosis) including idiopathic scoliosis, neuromuscular scoliosis, and congenital scoliosis. Additionally, the Black Diamond Pedicle Screw System is intended to treat pediatric patients diagnosed with spondylolisthesis/spondylolysis, fracture caused by tumor and/or trauma, pseudarthrosis, and/or failed previous fusion. This system is intended to be used with autograft and/or allograft. Pediatric pedicle screw fixation is limited to a posterior approach.
Summary of the technological characteristics compared to predicate	<u>Intended Use</u> The Black Diamond Pedicle Screw System and all the predicates have similar intended uses. <u>Materials</u> The Black Diamond Pedicle Screw System is fabricated from the same material as the predicate devices. <u>Design Features/Functions</u> The Black Diamond Pedicle Screw System and cited predicate devices share similar basic design features and functions. <u>Dimensions</u> The Black Diamond Pedicle Screw System is dimensionally similar to cited predicate devices. <u>Sterilization</u> The Black Diamond Pedicle Screw System is supplied non-sterile and cited predicate devices are non-sterile. <u>Performance Specification</u> Mechanical testing confirmed the Black Diamond Pedicle Screw System showed as good or better performance to the cited predicate devices under the same test conditions.
Non-clinical Test Summary	The following analyses were conducted: • Static and dynamic compression per ASTM F1717 • Static torsion per ASTM F1717 The results of these evaluations show that the Black Diamond Pedicle Screw System is equivalent to predicate devices.
Clinical Test Summary	No clinical studies were performed
Conclusions: Non-clinical and Clinical	Osseus Fusion Systems considers the Black Diamond Pedicle Screw System to be equivalent to the predicate devices listed above. This conclusion is based upon the devices' similarities in principles of operation, technology, materials, and indications for use.