January 28, 2021

Zimmer Biomet Spine, Inc.
Alex Pawlowski
Regulatory Affairs Project Manager
10225 Westmoor Drive
Westminster, Colorado 80021

Re: K203507
Trade/Device Name: Vitality® Spinal Fixation System
Regulation Number: 21 CFR 888.3070
Regulation Name: Thoracolumbosacral Pedicle Screw System
Regulatory Class: Class II
Product Code: NKB, KWP, KWQ
Dated: November 27, 2020
Received: November 30, 2020

Dear Mr. Pawlowski:

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 and Part 809; 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,

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)*

K203507

Device Name
Vitality® Spinal Fixation System

Indications for Use *(Describe)*

The Vitality® Spinal Fixation System implants are non-cervical spinal fixation devices intended for posterior pedicle screw fixation (T1-S2/ilium), posterior hook fixation (T1-L5), or anterolateral fixation (T8-L5). Pedicle screw fixation is indicated for skeletally mature patients and for adolescent patients.

These devices are indicated as an adjunct to fusion for all of the following indications: degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic sites), spondylolisthesis, trauma (i.e., fracture or dislocation), deformities or curvatures (i.e. scoliosis, kyphosis, and/or lordosis, Scheuermann's Disease), tumor, stenosis, pseudoarthrosis and/or failed previous fusion. When used as an adjunct to fusion, the Vitality® Spinal Fixation System is intended to be used with autograft and/or allograft.

In addition the Vitality® Spinal Fixation System is intended for treatment of severe spondylolisthesis (Grade 3 and 4) of the L5-S1 vertebra in skeletally mature patients receiving fusion by autogenous bone graft, having implants attached to the lumbosacral spine and or ilium with removal of the implant after attainment of a solid fusion. Levels of pedicle screw fixation for these patients are L3-sacrum/ilium.

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

The use of the vitality Spinal fixation System in skeletally mature patients may include the fixation of the Instinct® Java™ System hooks, APEX® System hooks, or fixation of the Universal Clamp® Spinal Fixation System to the rods of the Vitality Spinal Fixation System. The Vitality Spinal fixation System may also be used in skeletally immature patients when connected with the Universal Clamp Spinal Fixation System.

In order to achieve additional levels of fixation in skeletally mature patients, the Vitality Spinal Fixation System may be connected to the Virage® OCT Spinal Fixation System* and the Instinct Java Spinal Fixation System offered by Zimmer Biomet Spine, using rod connectors.

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

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR § 807.92.

Preparation Date	November 27, 2020
Applicant/Sponsor	Zimmer Biomet Spine, Inc. 10225 Westmoor Dr. Westminster, CO 80021
Contact Person	Alex Pawlowski Regulatory Affairs Project Manager Phone: 303-533-1062 Ted Kuhn Regulatory Affairs Director Phone: 303 319-4857
Trade Name	Vitality® Spinal Fixation System
Common Name	Pedicle Screw Spinal System
Device Class	Class II
Classification Name	Thoracolumbosacral Pedicle Screw System(NKB) Class II per 21 CFR §888.3070 Appliance, Fixation, Spinal Interlaminal (KWP) Class II per 21 CFR §888.3050 Appliance, Fixation, Spinal Intervertebral Body (KWQ) Class II per 21 CFR §888.3060
Device Panel	Orthopedic

Device Description & Technological Characteristics:

The Vitality® Spinal Fixation System is a thoracolumbar and sacroiliac fixation system designed to aid in the surgical correction of several types of spinal conditions. The system consists of a variety of spinal rods, pedicle screws, hooks, and connectors intended only to provide temporary stabilization during the development of a solid fusion of the spine with bone graft. The system can be rigidly locked into a variety of configurations, with each construct being customized to the patient's anatomy during surgery. All implants are single use only and should not be reused under any circumstances. The implant system is intended to be removed after solid fusion has occurred.

The system also includes instrumentation for insertion and removal and securing of the implants. All implants are made from medical grade titanium alloy; select rods are also available in medical grade cobalt chromium alloy. Implants made from medical grade titanium, medical grade titanium alloy, and medical grade cobalt chromium may be used together. Never use titanium, titanium alloy, and/or cobalt chromium with stainless steel in the same implant construct.

The Vitality Spinal Fixation System is compatible with the Virage® OCT Spinal Fixation System Rods, Instinct® Java™ Spinal Fixation System Rods and Hooks, and Universal Clamp® Spinal Fixation System.

Intended Use / Indications for Use:

The Vitality® Spinal Fixation System implants are non-cervical spinal fixation devices intended for posterior pedicle screw fixation (T1-S2/ilium), posterior hook fixation (T1-L5), or anterolateral fixation (T8-L5). Pedicle screw fixation is indicated for skeletally mature patients and for adolescent patients.

These devices are indicated as an adjunct to fusion for all of the following indications: degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic sites), spondylolisthesis, trauma (i.e., fracture or dislocation), deformities or curvatures (i.e. scoliosis, kyphosis, and/or lordosis, Scheuermann's Disease), tumor, stenosis, pseudoarthrosis and/or failed previous fusion. When used as an adjunct to fusion, the Vitality® Spinal Fixation System is intended to be used with autograft and/or allograft.

In addition the Vitality® Spinal Fixation System is intended for treatment of severe spondylolisthesis (Grade 3 and 4) of the L5-S1 vertebra in skeletally mature patients receiving fusion by autogenous bone graft, having implants attached to the lumbosacral spine and or ilium with removal of the implant after attainment of a solid fusion. Levels of pedicle screw fixation for these patients are L3-sacrum/ilium.

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In order to achieve additional levels of fixation in skeletally mature patients, the Vitality Spinal Fixation System may be connected to the Virage® OCT Spinal Fixation System* and the Instinct Java Spinal Fixation System offered by Zimmer Biomet Spine, using rod connectors.

Predicates:

Vitality® Spinal Fixation System (K183550, Primary Predicate) and the Sequoia® Pedicle Screw System (K131980).

Summary of Technologies:

The technological characteristics of the subject Vitality® Spinal Fixation System components remain the same as, or similar to, the predicate Vitality® Spinal Fixation System (K183550) in regards to intended use, indications for use, design, manufacturing methods, fundamental technology, and operational principles. The purpose of this submission is to seek clearance for minor modifications to the screw design.

Performance Data:

To support substantial equivalence, mechanical testing of the modified screw implants of the subject Vitality® Spinal Fixation System were assessed and tested appropriately in accordance with ASTM standards. Performance testing included tests per ASTM F1717 and ASTM F1798 which demonstrated the subject devices are safe and effective for use with pedicle screw fixation. In all instances, the modified device functioned as intended and demonstrated substantial equivalence to the predicate device(s).

Substantial Equivalence:

The subject Vitality® Spinal Fixation System is substantially equivalent to the Vitality® Spinal Fixation System (K183550) and the Sequoia® Pedicle Screw System (K131980).

Conclusion:

The Vitality® Spinal Fixation System is substantially equivalent to the predicate systems as a spinal fixation device in regards to intended use, indications for use, fundamental technology including design, materials, manufacturing methods, sterility, and operational principles. Furthermore, mechanical testing and other supporting information sufficiently demonstrate the substantial equivalence of the subject components to the Vitality® Spinal Fixation System and the Sequoia® Pedicle Screw System which have been cleared for non-cervical spinal fixation. Based on this information, the subject device does not raise any new issues regarding the safety or efficacy when compared to its predicates.