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	April 4, 2019
Device Submitter	Zimmer Biomet Spine, Inc. 10225 Westmoor Dr. Westminster, CO 80021
Contact Person	Brendon Heyerdahl Regulatory Affairs Specialist Phone: 303-501-8481 Ted Kuhn Regulatory Affairs Associate Director Phone: 720-469-5055
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

Primary Predicate Device Vitality® Spinal Fixation System, K171907
Additional Predicate Device PathFinder NXT® Minimally Invasive Pedicle Screw System, K132884

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. 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.

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.

Assembly of a spinal fixation construct using the Vitality® Spinal Fixation System may include additionally any Instinct® Java™ System hook, any APEX® System hook, or the Universal Clamp® (titanium). These direct-connect single point of fixation implants act in concert with the Vitality® System rods and implants to support its surgical indications for use.

In order to achieve additional levels of fixation, the Vitality® Spinal Fixation System rods may be connected to the Instinct® Java™ System (Ø5.5mm rod) or the Virage® OCT Spinal Fixation System (Ø3.5mm rod) with the corresponding Vitality® rod connectors. Refer to the Instinct® Java™ System and Virage® OCT Spinal Fixation System package inserts for instructions and indications for use.

Summary of Technologies:

The technological characteristics of the subject Vitality® Spinal Fixation System components remain the same as, or similar to, the primary predicate Vitality® Spinal Fixation System (K171907) 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, the addition of hooks, and the addition of associated instruments.

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 (dynamic compression bending) and 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 (K171907).

Conclusion:

The Vitality® Spinal Fixation System is substantially equivalent to the predicate system 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 which have been cleared for non-cervical spinal fixation and a minimally invasive surgical approach respectively. Based on this information, the subject device does not raise any new issues regarding the safety or efficacy when compared to its predicates.