



ZimVie Spine (Zimmer Biomet Spine, Inc.)
Hanna Aucoin
Regulatory Affairs Senior Specialist
10225 Westmoor Drive
Westminster, Colorado 80021

October 11, 2023

Re: K230116

Trade/Device Name: Vital™ Spinal Fixation System
Regulation Number: 21 CFR 888.3070
Regulation Name: Thoracolumbosacral Pedicle Screw System
Regulatory Class: Class II
Product Code: NKB
Dated: September 7, 2023
Received: September 8, 2023

Dear Hanna Aucoin:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (<https://www.fda.gov/media/99812/download>) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (<https://www.fda.gov/media/99785/download>).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

 Digitally signed
by Eileen Cadel -
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Date: 2023.10.11
10:48:56 -04'00'

for

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

Indications for Use

510(k) Number (*if known*)
K230116

Device Name
Vital™ Spinal Fixation System

Indications for Use (*Describe*)

The Vital/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 studies), 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 Vital/Vitality Spinal Fixation System is intended to be used with autograft and/or allograft.

In addition the Vital/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 Vital/Vitality System implants are indicated as an adjunct to fusion to treat adolescent idiopathic scoliosis. The Vital/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 Vital/Vitality Spinal Fixation System in skeletally mature patients may include the fixation of the Instinct® Java™ Spinal Fixation System* hooks, APEX Spinal System™* hooks, or fixation of the Universal Clamp® Spinal Fixation System* to the rods of the Vital/Vitality Spinal Fixation System. The Vital/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 Vital/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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10/11/2023

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.

Sponsor Information	
Name	Zimmer Biomet Spine, Inc. (d/b/a ZimVie Spine)
Address	10225 Westmoor Dr. Westminster, CO 80021
Establishment Registration	3012447612
Contact Person(s)	Hanna Aucoin Regulatory Affairs Senior Specialist Phone : (816) 562.2948 Email : Hanna.Aucoin@zimvie.com
	Alex Pawlowski Regulatory Affairs Director Phone : (303) 264.8255 Email : Alex.Pawlowski@zimvie.com

Device Information	
Proprietary Name	Vital™ Spinal Fixation System
Common Name	Pedicle Screw Spinal Fixation System
Device Class	Class II
Device Panel	Orthopedic Panel (87)
Regulation Number	21 CFR § 888.3070
Classification Name-Product Code(s)	Thoracolumbosacral Pedicle Screw System (NKB)
Predicate Devices	Primary Predicate: <i>Vital™ Spinal Fixation System (K203507)</i>

Device Description

The Vital™ 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, securing and removal 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 Vital™ Spinal Fixation System is compatible with components from other cleared spinal fixation systems.

Intended Use / Indications for Use

The Vital/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 studies), 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 Vital/Vitality Spinal Fixation System is intended to be used with autograft and/or allograft.

In addition the Vital/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 Vital/Vitality System implants are indicated as an adjunct to fusion to treat adolescent idiopathic scoliosis. The Vital/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 Vital/Vitality Spinal Fixation System in skeletally mature patients may include the fixation of the Instinct® Java™ Spinal Fixation System* hooks, APEX Spinal System™* hooks, or fixation of the Universal Clamp® Spinal Fixation System* to the rods of the Vital/Vitality Spinal Fixation System. The Vital/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 Vital/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.

Substantial Equivalence Assessment

The technological characteristics of the subject Vital™ Spinal Fixation System components remain the same as, or similar to, the predicate Vital™ Spinal Fixation System (K203507) in regard to intended use, indications for use, design, manufacturing methods, fundamental technology, and operational principles. The purpose of this submission is to seek clearance of the MRI conditional information provided in the Instructions for Use for the Vital™ Spinal Fixation System. Additionally, this submission discloses various minor changes to the previously cleared Vital™ Spinal Fixation System that were introduced via Letters-to-File.

Specifically, the subject Vital™ Spinal Fixation System is manufactured using the same materials and processes used to manufacture the previously cleared Vital System. Additionally, the subject devices have the same intended use as the predicate devices. As such, the performance assessments of the subject devices are substantially equivalent to the predicate devices. Furthermore, the subject Vital™ Spinal Fixation System has the same methods and technological characteristics as its cleared predicate Vital™ Spinal Fixation System (K203507).

Performance Testing

Results from the Magnetic Resonance Imaging evaluation demonstrate that the Vital™ Spinal Fixation System is MR Conditional in accordance with ASTM F2052, ASTM 2182, and ASTM 2213. Data and scientific rationales were used to quantify the RF-induced heating, static magnetic field interactions, and image artifact generation of the Vital™ Spinal Fixation System in the 1.5 Tesla (T) and 3.0 T MRI clinically relevant environments.

Substantial Equivalence Conclusion

The subject Vital™ Spinal Fixation System's indications for use, intended use, design, materials, and performance assessments are substantially equivalent to the currently marketed Vital™ Spinal Fixation System. Furthermore, the addition of "MR Conditional" information on the labeling does not impact the safety and effectiveness of the system. As such, Zimmer Biomet Spine, Inc. concludes that the subject Vital™ Spinal Fixation System is substantially equivalent to the predicate Vital™ Spinal Fixation System.