December 17, 2025

Highridge Medical, LLC
Eliot Teal
Regulatory Affairs Specialist
10225 Westmoor Drive
Westminster, Colorado 80021

Re: K253093
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, KWP, KWQ
Dated: September 23, 2025
Received: September 23, 2025

Dear Eliot Teal:

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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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,

EILEEN CADEL -S 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

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K253093

Please provide the device trade name(s).

Vital™ Spinal Fixation System

Please provide your Indications for Use below.

The Vital Spinal Fixation System implants are non-cervical spinal fixation devices intended for posterior pedicle screw fixation (T1S2/ilium), posterior hook fixation (T1L5), or anterolateral fixation (T8L5). 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 Vitality Spinal Fixation System is intended to be used with autograft and/or allograft.

In addition the Vital 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 System implants are indicated as an adjunct to fusion to treat adolescent idiopathic scoliosis. The Vital System is intended to be used with autograft and/or allograft. Pediatric pedicle screw fixation is limited to a posterior approach.

PRODUCT COMPATIBILITY

The use of the Vital 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 Spinal Fixation System. The Vital Spinal Fixation System may also be used in skeletally immature patients when connected with the Universal Clamp Spinal Fixation System.

The Vital Spinal Fixation System implants are compatible with the KHEIRON® Spinal Fixation System patient specific K-ROD when used in posterior approach.

In order to achieve additional levels of fixation in skeletally mature patients, the Vital 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.

Please select the types of uses (select one or both, as applicable).

- ☒ Prescription Use (Part 21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

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	Highridge Medical, LLC
Address	10225 Westmoor Dr. Westminster, CO 80021
Establishment Registration	3012447612
Contact Person(s)	Eliot Teal Regulatory Affairs Specialist Phone : (704) 258.9255 Email : Eliot.Teal@highridgemedical.com
	Anjanet Mort Regulatory Affairs Manager Phone (720) 839.7926 Email : Anjanet.Mort@highridgemedical.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, KWP, KWQ)
Predicate Devices	Primary: Vital™ Spinal Fixation System (K240539) Additional: KHEIRON® Spinal Fixation System, including patient specific K-ROD (K232650)

Device Description

The Vital™ (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, 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™ MIS System is a percutaneous screw delivery system that is an extension of the Vital™ System. The Vital MIS System implants consist of a variety of spinals rods and pedicle screws that are modified under the MIS line extension to feature cannulated screws (extended and non-extended tab) and modified spinal rods (bullet nose, connection, curvature). The system includes a variety of instrumentation which are also compatible with Vital and Vital MIS implant offerings in the Vital™ System and allow for a minimalized, percutaneous, or mini-open surgical approach, extending MIS capabilities to the cannulated implants of the wider Vital™ System.

Intended Use / Indications for Use

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

In addition, the Vital 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 System implants are indicated as an adjunct to fusion to treat adolescent idiopathic scoliosis. The Vital System is intended to be used with autograft and/or allograft. Pediatric pedicle screw fixation is limited to a posterior approach.

PRODUCT COMPATIBILITY

The use of the Vital 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 Spinal Fixation System. The Vital Spinal Fixation System may also be used in skeletally immature patients when connected with the Universal Clamp Spinal Fixation System.

The Vital Spinal Fixation System implants are compatible with KHEIRON® Spinal Fixation System patient specific K-ROD when used in a posterior approach.

In order to achieve additional levels of fixation in skeletally mature patients, the Vital 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

There are no changes between the predicate and subject system as no new components have been added to the system. The technological characteristics of the subject Vital System remain the same as, or similar to the predicate Vital System (K240539) in regard to intended use, indications for use, design, manufacturing methods, fundamental technology, and operational principles.

This submission establishes compatibility of the Vital System with the patient specific-K-ROD from the KHEIRON Spinal Fixation System (K232650), manufactured by SMAIO. When used in place of a Vital System rod in a Vital System construct, K-RODs are substantially equivalent in materials, dimensions, and performance. Performance testing of the worst-case Vital System – K-ROD construct was evaluated in accordance ASTM F1717 (dynamic compression bending) and ASTM F1798 (axial and torsional grip) and met all acceptance criteria.

Additionally, an RF Induced Heating evaluation in accordance with ASTM F2182-19e2 in a bone-inclusive phantom was completed to support an update to the system's MR Conditional parameters. Results of the evaluation demonstrated that the Vital System remains safe for use in an MR setting under conditional parameters.

Labeling is also updated to include automated cleaning instructions compliant with ANSI/AAMI ISO 17664-1:2022. Evaluation demonstrated that the Vital System does not present a new worst-case to validated automated cleaning parameters.

Substantial Equivalence Conclusion

The subject Vital System's indications for use, intended use, scientific technology, operational principles, and performance assessments are substantially equivalent to the currently marketed Vital System. As such, Highridge Medical concludes that the subject Vital System is substantially equivalent to the predicate Vital System.