December 17, 2025

S.M.A.I.O
% Robert Poggie
President
BioVera, Inc.
65 Promenade Saint Louis
Notrre-Dame-De-L'Ile-Perrot, QC J7W3J6
Canada

Re: K253721
Trade/Device Name: KHEIRON® Spinal Fixation System, including patient specific K-ROD
Regulation Number: 21 CFR 888.3070
Regulation Name: Thoracolumbosacral pedicle screw system
Regulatory Class: Class II
Product Code: NKB, KWP
Dated: November 24, 2025
Received: November 24, 2025

Dear Robert Poggie:

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,

Colin O'neill -S

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.	K253721

Please provide the device trade name(s).

KHEIRON® Spinal Fixation System, including patient specific K-ROD

Please provide your Indications for Use below.

KHEIRON® Spinal Fixation System including patient specific K-ROD 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 stenosis, spinal tumor, pseudarthrosis and failed previous fusion.

When used for posterior, non-cervical, pedicle screw fixation in pediatric patients, KHEIRON® Spinal Fixation System including patient specific K-ROD is 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, KHEIRON® Spinal Fixation System including patient specific K-ROD 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.

Patient specific K-ROD devices are compatible with NuVasive Reline System components that are only compatible with Ø5.5mm and/or Ø6.0mm rods as well as screws Ø4.5mm or larger and at least 25mm in length.

Patient specific K-ROD devices are compatible with Seaspine Mariner System components that are compatible with Ø5.5mm and/or Ø6.0mm rods as well as screws Ø4.5mm or larger and at least 25mm in length.

Patient specific K-ROD devices are compatible with Vital™ Spinal Fixation System components that are compatible with ø5.5mm and/or ø6.0mm rods as well as screws ø4.0mm or larger and at least 20mm in length.

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)

Special 510(k) Device Modification

KHEIRON® Spinal Fixation System including patient specific K-ROD

In accordance with 21 CFR 807.92 of the Federal Code of Regulations, the following is a summary of safety and effectiveness of the KHEIRON® Spinal Fixation System, including patient specific K-ROD, and compatibility with the Vital™ Spinal Fixation System.

A. SUBMITTERS INFORMATION

Submitter Name:	BioVera, Inc.
Submitter Address:	65 Promenade Saint-Louis, NDIP, Québec, J7W 3J6, CANADA
Contact Person:	Robert A. Poggie, PhD
Phone Number:	514-349-7226
Date of Submission:	December 17, 2025

B. DEVICE IDENTIFICATION & MANUFACTURER

Manufacturer Name:	S.M.A.I.O
Manufacturer Address:	2 place Berthe Morisot - Parc Technologique 69800 Saint Priest - FRANCE
Registration Number:	3015383864
Contact Name:	Jean-Charles ROUSSOULY
Title:	Deputy CEO
Device Trade Name:	KHEIRON® Spinal Fixation System, including patient specific K-ROD
Regulation Name:	Thoracolumbosacral Pedicle Screw System
Regulation Numbers:	21 CFR 888.3070, 21 CFR 888.3050
Classification Codes:	Primary code: NKB Additional code: KWP
Classification Panel:	Orthopedic

C1. PRIMARY PREDICATE DEVICE

K211981, K232650, K251804	KHEIRON® Spinal Fixation System, including patient specific K-ROD

C2. ADDITIONAL PREDICATE DEVICE

K240539	Vital™ Spinal Fixation System

D. DEVICE DESCRIPTION

S.M.A.I.O.'s patient specific K-ROD is part of the 510(k) cleared KHEIRON® Spinal Fixation system (K211981, K232650, K251804) designed for stabilization and correction of chronic instability or deformity of the thoracic, lumbar, and sacral spine. The patient specific K-ROD is made from Ti-6Al-4V ELI per ASTM F136 and is available in diameters of 5.5 and 6.0 mm.

The Vital™ Spinal Fixation System is a 510(k) cleared pedicle screw system (K240539) that consists of a variety of screws, hooks, rods, lock screws, transverse connectors, rod-to-rod connectors, iliac connectors, and general instruments. Implant components are available in a variety of sizes and can be rigidly locked into a variety of different configurations to suit the individual pathology and anatomical conditions of the patient. The Vital™ Spinal Fixation System is designed to provide immobilization and stabilization of spinal segments as an adjunct to fusion in the treatment of acute and chronic instabilities or deformities of the posterior thoracic, lumbar, and sacral spine. The Vital™ Spinal Fixation System is also used to treat severe spondylolisthesis (Grades 3 and 4) of the L5-S1 vertebral joint in skeletally mature patients receiving fusion by autogenous bone graft.

The purpose of this Special 510(k) Device Modification is to extend S.M.A.I.O.'s patient specific K-ROD (K211981, K232650, K251804) for use with the Vital™ Spinal Fixation System (K240539).

E. INDICATIONS FOR USE

KHEIRON® Spinal Fixation System including patient specific K-ROD 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 stenosis, spinal tumor, pseudarthrosis and failed previous fusion.

When used for posterior, non-cervical, pedicle screw fixation in pediatric patients, KHEIRON® Spinal Fixation System including patient specific K-ROD is 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, KHEIRON® Spinal Fixation System including patient specific K-ROD 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.

Patient specific K-ROD devices are compatible with NuVasive Reline System components that are only compatible with Ø5.5mm and/or Ø6.0mm rods as well as screws Ø4.5mm or larger and at least 25mm in length.

Patient specific K-ROD devices are compatible with Seaspine Mariner System components that are compatible with Ø5.5mm and/or Ø6.0mm rods as well as screws Ø4.5mm or larger and at least 25mm in length.

Patient specific K-ROD devices are compatible with Vital™ Spinal Fixation System components that are compatible with ø5.5mm and/or ø6.0mm rods as well as screws ø4.0mm or larger and at least 20mm in length.

F. TECHNOLOGICAL CHARACTERISTICS, COMPARISON TO PREDICATE DEVICE

The patient specific K-ROD subject device is identical to the patient specific K-ROD cleared in K211981, K232650, and K251804. The components of the Vital™ Spinal Fixation System that interface with the patient specific K-ROD are identical to those cleared in K240539. The purpose of this Special 510(k) is to present the V&V activities demonstrating that the K-ROD can be used with the Vital™ Spinal Fixation System.

Intended Use: K-RODs used in conjunction with the Vital™ Spinal Fixation System, and the predicate devices are intended to be used to maintain spine shape until fusion occurs.

Indications for Use: The indications for use statement for the primary predicate and subject devices are the same.

Material: K-RODs used in conjunction with the Vital™ Spinal Fixation System uses the same material as the predicates (ASTM F136 Ti-6Al-4V alloy).

Design: K-RODs used in conjunction with the Vital™ Spinal Fixation System and the predicate devices are substantially equivalent in shape, sizes, material, and manufacturing process.

Strength: K-ROD used with the Vital™ Spinal Fixation System has similar strength as the primary predicate K-ROD per verification and validation activities.

G. PERFORMANCE DATA

Engineering analysis and mechanical testing of K-RODs used with the Vital™ Spinal Fixation System were performed to validate the mechanical characteristics of the expanded use of patient specific K-RODs. The following mechanical tests were performed:

- Dynamic compression bending – ASTM F1717
- Static axial gripping capacity – ASTM F1798
- Static torsional gripping capacity – ASTM F1798

The ASTM F1717 and F1798 tests performed for V&V of K-ROD used with the Vital™ Spinal Fixation System were identical in set-up and test parameters presented in K211981, K232650, and K251804. Engineering analysis comparing K-ROD and Vital™ Spinal Fixation System's titanium alloy rods determined that a new worst-case was not created and that subject and predicate devices are substantially equivalent.

H. CONCLUSIONS

The information presented in this Special 510(k) Device Modification demonstrates that the KHEIRON® Spinal Fixation System, including patient specific K-ROD, is compatible with the Vital™ Spinal Fixation System as described in this 510(k) and is substantially equivalent to the legally marketed predicate devices.