



April 3, 2026

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

Re: K260786

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: March 10, 2026
Received: March 10, 2026

Dear Robert A. 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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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.

K260786

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Please provide the device trade name(s).

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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.

When connected to compatible pedicle screw systems, the 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.

Please refer to the additional information section of the most up-to-date Instructions for Use on compatible pedicle screw systems.

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

Prescription Use ([21 CFR 801 Subpart D](#))

Over-The-Counter Use ([21 CFR 801 Subpart C](#))

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Please select the age group(s) for which the device(s) is to be used.

Neonates/Newborns (Birth to < 29 days old)

Infants (29 days old to < 2 years old)

Children (2 years old to < 12 years old)

Adolescents (12 years old to < 22 years old)

Adults (22 years old and greater)

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Special 510(k) Device Modification - K260786

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 Orthofix Virata Spine 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: April 1, 2026

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,
K253721, K253990** KHEIRON® Spinal Fixation System, including
patient specific K-ROD

C2. ADDITIONAL PREDICATE DEVICES

K250908 Orthofix Virata Spinal Fixation System

D. DEVICE DESCRIPTION

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, K253721, K253990) for use with the Orthofix Virata Spinal Fixation System (K250908). S.M.A.I.O.'s patient specific K-ROD is part of the 510(k) cleared KHEIRON Spinal Fixation system (K211981, K232650, K251804, K253721, K253990) 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 Orthofix Virata Spinal Fixation System is a non-cervical spinal fixation device and instrumentation system (K250908) that is intended for use as a posterior pedicle screw fixation system, a posterior non-pedicle fixation system, or as an anterolateral fixation system. The system consists of single-use implants including shanks, tulips, screw bodies, set screws, and spinal rods. The Virata 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.

Patient specific K-ROD devices are compatible with:

- NuVasive Reline System components and Orthofix Mariner Systems components that are compatible with \varnothing 5.5mm and/or \varnothing 6.0mm rods as well as screws \varnothing 4.5mm or larger and at least 25mm in length
- Highridge Vital Spinal Fixation System components that are compatible with \varnothing 5.5mm and/or \varnothing 6.0mm rods as well as screws \varnothing 4.0mm or larger and at least 20mm in length
- Expedium and TriALTIS Spine systems components that are compatible with \varnothing 5.5mm and/or \varnothing 6.0mm rods as well as screws \varnothing 4.35mm or larger for Expedium Spine system and fenestrated screws \varnothing 4.50mm or larger for TriALTIS Spine system
- Patient specific K-ROD devices are compatible with Orthofix Mariner System components that are compatible with \varnothing 5.5mm and/or \varnothing 6.0mm rods as well as screws \varnothing 4.5mm or larger and at least 25mm in length
- Patient specific K-ROD devices are compatible with Orthofix Virata System components that are compatible with \varnothing 5.5mm and/or \varnothing 6.0mm rods as well as screws \varnothing 4.0mm or larger and at least 20mm in length

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.

When connected to compatible pedicle screw systems, the 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.

Please refer to the additional information section of the most up-to-date Instructions for Use on compatible pedicle screw systems.

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, K251804, K253721, and K253990. The components of the Orthofix Virata System are identical to those cleared in K250908. The purpose of this Special 510(k) is to present the V&V activities demonstrating that the patient specific K-ROD can be used with the Orthofix Virata System.

Intended Use: K-RODs used in conjunction with the Orthofix Virata 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 Orthofix Virata System use the same material as the predicates (ASTM F136 Ti-6Al-4V alloy).

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

Strength: K-RODs used with the Orthofix Virata 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 Orthofix Virata 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 Orthofix Virata System were identical in set-up and test parameters presented in K211981, K232650, K251804, K253721, and K253990. Engineering analysis comparing K-ROD and Orthofix Virata System 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 Orthofix Virata System as described in this 510(k) and is therefore substantially equivalent to the legally marketed predicate devices.