July 1, 2026

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

Re: K253802
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: June 17, 2026
Received: June 17, 2026

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 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.

K253802

Please provide the device trade name(s).

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

Please provide your Indications for Use below.

The 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, the KHEIRON Spinal Fixation System implants are 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, the KHEIRON Spinal Fixation System is intended to treat pediatric patients diagnosed with spondylolisthesis/spondylolysis, fracture caused by tumor and/or trauma, pseudarthrosis, and/or failed previous fusion.

The system is intended to be used with autograft and/or allograft.

Pediatric pedicle screw fixation is limited to a posterior approach.

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

- [x] Prescription Use (Part 21 CFR 801 Subpart D)
- [ ] Over-The-Counter Use (21 CFR 801 Subpart C)

510(k) Notification for the
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.

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:	June 17, 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	KHEIRON® Spinal Fixation System including patient specific K-ROD

C2. ADDITIONAL PREDICATE DEVICES

K201659	KHEIRON® Spinal Fixation System
K211414	KHEIRON® Spinal Fixation System
K140738	PASS LP Spinal System
K243007	Medtronic Horizon System

D. DEVICE DESCRIPTION

The KHEIRON® Spinal Fixation System (K201659 and K211414) is comprised of rods, pedicle screws, hooks, and cross-links made from Ti-6Al-4V alloy (ASTM F136) that are designed for stabilization and correction of chronic instability or deformity of the thoracic, lumbar, and sacral spine. Patient specific, pre-bent Ti-6Al-4V alloy K-ROD rods were a line extension to the KHEIRON Spinal Fixation System via K211981. The primary predicate device for this 510(k) notification is the KHEIRON Spinal Fixation System with patient specific K-ROD (K211981).

The purpose of this 510(k) notification is to extend the range of 510K cleared (K201659, K211414, K211981) KHEIRON® Spinal Fixation System rods and patients specific K-ROD to include K-RODs made from CoCrMo alloy per ASTM F1537-20. There are no other changes in design and intended use to the predicate devices other than the material change from Ti-6Al-4V alloy to CoCrMo alloy.

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.

The system is intended to be used with autograft and/or allograft.

Pediatric pedicle screw fixation is limited to a posterior approach.

F. TECHNOLOGICAL CHARACTERISTICS, COMPARISON TO PREDICATE DEVICE

The subject device KHEIRON® Spinal Fixation System including patient specific K-ROD is identical to the primary predicate device cleared in K211981, trade named the KHEIRON® Spinal Fixation System including patient specific K-ROD. The new technological feature of the subject device are the rods being made from ASTM F1537-20 CoCrMo alloy, whereas the rods for the primary predicate device are made from titanium alloy per ASTM F136.

Intended Use: The indicated and intended uses of the subject and primary predicate devices are identical; namely to provide for stabilization and correction of chronic instability or deformity of the thoracic, lumbar, and sacral spine as an adjunct to fusion.

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

Design: The design of all of the components of the subject device are identical to that of the primary predicate device, including the rods (straight, curved, patient-specific K-ROD).

Material: The rods (straight, curved, patient-specific K-ROD) for the subject device are manufactured from ASTM F1537 CoCrMo alloy. The rods (straight, curved, patient-specific K-ROD) for the primary predicate device are manufactured from ASTM F136 Ti-6Al-4V ELI alloy.

Strength / construct integrity: The CoCrMo rods for the subject device were determined possess higher grip strength (axial and torsion per ASTM F1798).

G. PERFORMANCE DATA

The addition of rods made of CoCrMo alloy to the KHEIRON® Spinal Fixation System including patient specific K-ROD necessitated the following tests and analyses:

- Engineering analysis and mechanical testing of the rods made of CoCrMo alloy were performed to verify and validate the mechanical characteristics of the subject device, relative to previous testing reported in cleared K201659 for the same size rods made of titanium alloy (ASTM F136). The risk and engineering analyses resulted in performance of static axial and static torsional testing of worst case devices per ASTM F1798. The ASTM F1798 test performed on the subject devices were identical in set-up and parameters presented and cleared in K201659 for the predicate device. The results showed the static and axial and torsional strength of the subject CoCrMo rods to be higher than that of the primary predicate titanium alloy rods.
- Biological risk was assessed per ISO 14971 for risk and ISO 10993-1 for biocompatibility. The results demonstrated that the subject devices were biocompatible per ISO 10993-1 and the associated FDA guidance document.
- Sterilization (steam autoclave) was revalidated for the CoCrMo rods for a worst case load / set of subject devices for a Sterility Assurance Level (SAL) of minimum 10^{-6} using the overkill method with partial cycle per ISO 17665:2024, Appendix B. The results demonstrated the original cleaning and sterilization instructions (in K211981) were valid for the subject devices.

H. CONCLUSIONS

The information presented in this 510(k) notification demonstrates that the rod components of the KHEIRON® Spinal Fixation System including patient specific K-ROD made from CoCrMo alloy are substantially equivalent to the Ti-6Al-4V alloy rod components of the primary predicate device (K211981).