



September 29, 2023

S.M.A.I.O.

% Robert A. Poggie, Ph.D.

President

BioVera, Inc.

65 Promenade Saint Louis

Notre Dame de l'Île Perrot, Quebec J7W3J6

Canada

Re: K232650

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: August 30, 2023

Received: August 31, 2023

Dear Dr. 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.

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,

Brent Showalter -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

510(k) Number (if known)
K232650

Device Name

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

Indications for Use (Describe)

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 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, the 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 compatible with $\varnothing 5.5\text{mm}$ and/or $\varnothing 6.0\text{mm}$ rods as well as screws $\varnothing 4.5\text{mm}$ or larger and at least 25mm in length.

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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Special 510(k) Device Modification, K232650
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 NuVasive's Reline 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: 514-901-0796
Date of Submission: August 30, 2023

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: Vice-President Operations
Device Trade Name: KHEIRON® Spinal Fixation System, including patient specific K-ROD
Regulation Name: Thoracolumbosacral Pedicle Screw System
Regulation Number: 21 CFR sections 888.3070
Classification Codes: Primary code: NKB Additional code: KWP
Classification Panel: Orthopedic

C1. PRIMARY PREDICATE DEVICE

K211981 KHEIRON® Spinal Fixation System

C2. ADDITIONAL PREDICATE DEVICE

K223181 NuVasive Reline 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) designed for stabilization and correction of chronic instability or deformity of the thoracic, lumbar, and sacral spine. The patient specific K-ROD is manufactured from Ti-6Al-4V ELI per ASTM F136 and is available in diameters of 5.5 and 6.0 mm.

The NuVasive Reline System is a 510(k) cleared pedicle screw system (K223181) 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 NuVasive Reline 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 NuVasive Reline 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 indication of S.M.A.I.O.'s patient specific K-ROD (K211981) for use with the NuVasive Reline System (K223181).

E. INDICATIONS FOR USE

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 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, the 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 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.

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. The components of the NuVasive Reline System that interface with the patient specific K-ROD are identical to those cleared in K223181. The purpose of this Special 510(k) is to present the V&V activities demonstrating that the K-ROD can be used with the NuVasive Reline System.

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

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

Strength: K-ROD used with the NuVasive Reline 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 NuVasive Reline System were performed to verify and validate the mechanical characteristics of the expanded use of patient specific K-RODs. The following mechanical tests were performed as part of the V&V activities:

- Static and dynamic – ASTM F1717
- Static torsion – 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 NuVasive Reline System were identical in set-up and test parameters as presented in K211981. Engineering analysis comparing K-ROD and NuVasive Reline System's titanium alloy rods determined that a new worst-case was not created for the K-ROD used with the NuVasive Reline System relative to the primary predicate K-ROD and predicate NuVasive Reline System devices.

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 NuVasive Reline System as described herein and is therefore substantially equivalent to the legally marketed predicate devices.