August 10, 2021

S. M. A. I. O
℅ Robert Poggie
President
BioVera, Inc.
65 Promenade Saint Louis
Noltre Dame de L'lle Perrot, Quebec J7V7P2
Canada

Re: K211414
Trade/Device Name: KHEIRON® Spinal Fixation System
Regulation Number: 21 CFR 888.3070
Regulation Name: Thoracolumbosacral Pedicle Screw System
Regulatory Class: Class II
Product Code: NKB, KWP
Dated: May 5, 2021
Received: May 6, 2021

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 (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 located 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.

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 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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, 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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

K211414

Device Name

KHEIRON® Spinal Fixation System

Indications for Use *(Describe)*

The KHEIRON® Spinal Fixation System 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.
This system is intended to be used with autograft and/or allograft. Pediatric pedicle screw fixation is limited to a posterior approach.

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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510(k) SUMMARY for K211414

In accordance with 21 CFR 807.92 of the Federal Code of Regulations, the following is a summary of safety and effectiveness of S.M.A.I.O.'s KHEIRON Spinal Fixation System.

A. SUBMITTERS INFORMATION

Submitter Name:	BioVera, Inc.
Submitter Address:	65 Promenade Saint-Louis, NDIP, Québec, J7V 7P2, CANADA
Contact Person:	Robert A. Poggie, PhD
Phone Number:	514-901-0796
Fax Number:	514-901-0796
Date of Submission:	May 4, 2021

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:	Operations vice-president
Device Trade Name:	KHEIRON® Spinal Fixation System
Device Common Name:	Pedicle Screw Spinal System
Classification Name:	Thoracolumbosacral Pedicle Screw System
Classification Codes:	Primary code: NKB Additional code: KWP
Classification Panel:	Orthopedic
Regulation Number:	Primary regulation: 21 CFR section 888.3070 Additional regulation: 21 CFR section 888.3050

C1. PRIMARY PREDICATE DEVICE

K201659	KHEIRON® Spinal Fixation System

C2. PREDICATE DEVICES

K020247	COLORADO 2™ Spinal System, Medtronic Sofamor Danek

D. DEVICE DESCRIPTION

The KHEIRON® Spinal Fixation System is used in a variety of conditions that affect the thoracic and lumbar spine. In cases in which the posterior elements are fractured, the pedicle screw offers an excellent means of stabilizing a specific spinal segment. The KHEIRON Spinal Fixation System includes screws, anchoring, connecting components, hooks, iliac extensions, and crosslinks in a range of sizes and shapes that can be locked in various configurations, with each assembly being tailor-made to the patient's anatomical condition. The KHEIRON pedicle screws must be used with 5.5mm and 6.0mm rods. KHEIRON spinal implants are made of Ti-6Al-4V ELI alloy that conforms to ASTM F136. The KHEIRON Spinal Fixation System is provided clean, non-sterile, and the implants are single-use only.

E. INDICATIONS FOR USE

The KHEIRON® Spinal Fixation System 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.

This 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

Intended Use: The KHEIRON Spinal Fixation System, including hooks, iliac extensions, and crosslinks (line extension), and the predicate devices are intended to be used to maintain adequate disc space until fusion occurs.

Indications for Use: The subject and predicate devices comply with the indications for use specified in 21 CFR section 888.3070 for thoracolumbosacral pedicle screw

systems. The indications for use statement for the primary predicate and subject devices are identical.

Material: The KHEIRON Spinal Fixation System uses the same material as the predicates (ASTM F136 Ti-6Al-4V alloy).

Design: The KHEIRON Spinal Fixation System and line extension and the predicate devices are substantially equivalent in shape, sizes, material, and manufacturing process.

Strength: The KHEIRON Spinal Fixation System with line extension has greater or substantially equivalent strength values compared to other devices cleared for use in the thoracolumbosacral spine, as demonstrated in performance testing to the predicate devices cited herein.

G. PERFORMANCE DATA

Engineering analysis and mechanical testing of the KHEIRON Spinal Fixation System line extension and predicate devices were performed for the purpose of measuring and comparing the mechanical characteristics of the devices. The following mechanical tests were performed:

- Static and dynamic compression bending – ASTM F1717
- Static torsion – ASTM F1717

Engineering analyses of various configurations of the KHEIRON Spinal Fixation System determined that a new worst-case was not created by the components of this line extension, relative to the predicate devices. The results of the engineering analyses and mechanical testing indicate that the line extensions, including hooks, iliac extensions, and crosslinks of the KHEIRON Spinal Fixation System are biomechanically equivalent to the predicate devices.

H. CONCLUSIONS

The data presented in this 510(k) notification demonstrates that the KHEIRON Spinal Fixation System with line extension components is substantially equivalent to the legally marketed predicate devices.