June 9, 2022

S.m.a.i.o.
% J.D. Webb
Official Correspondent
The OrthoMedix Group, Inc.
4313 W. 3800 S.
West Haven, Utah 84401

Re: K211981
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
Dated: June 1, 2022
Received: June 3, 2022

Dear J.D. Webb:

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,

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K211981

Device Name
KHEIRON® Spinal Fixation System

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 implants are indicated as an adjunct to fusion to treat progresive spinal deformities (i.e. scoliosis, kyphosis, or lordosis) including idiopathic scoliosis, neuromuscular scoliosos, 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.

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

In accordance with the requirements of the Safe Medical Device Act of 1990 and 21 CFR 807.92, S.M.A.I.O. is hereby submitting this 510(k) Summary.

1. Date Prepared

June 22, 2021

2. Submitter [510(k) owner]

S.M.A.I.O.
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3. Primary Contact

J.D. Webb
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512-590-5810 Tele
e-mail: jdwebb@orthomedix.net

4. Submitted Device Information

Trade Name: KHEIRON® Spinal Fixation System
Common Name: Thoracolumbosacral Pedicle Screw System

5. Classification Information

Classification: Class II
Classification Regulation: 21 CFR 888.3070
Classification Product Code: NKB
Classification Name: Thoracolumbosacral pedicle screw system
Device Panel: Orthopedic

6. Legally Marketed Predicate Devices

The K-ROD manufactured by S.M.A.I.O is substantially equivalent to the following devices currently in commercial use:

Primary Predicate Device

Device: KHEIRON® Spinal Fixation System and more specifically its curved rods 24CR55XXX and 24CR60XXX.
Company: S.M.A.I.O
510(k) number: K201659

Additional Predicate Devices

Device: PASS LP Spinal System
Company: Medicrea international
510(k) number: K140738

7. Submitted Device Description

K-RODs are titanium alloys bent rods, available in diameters 5.5mm and 6mm, which shape is a 3D spline designed to meet the need of specific correction of a patient.

K-RODs are to be used as a part of the KHEIRON® Spinal Fixation System (K201659) to reach intended use. KHEIRON® Spinal Fixation System is intended to help provide immobilization and stabilization of spinal segments as an adjunct to fusion of the thoracic, lumbar, and/or sacral spine. The KHEIRON® Spinal Fixation System may be used for a variety of conditions that affect the thoracic and lumbar spine. In cases in which the posterior elements are fractured, the spinal fixation system offers an excellent mean of stabilizing of a specific spinal segment. KHEIRON® Spinal Fixation System includes screws, rods and connecting components in a wide variety of sizes and shapes, which can be locked in various configurations, each assembly being tailor-made. KHEIRON pedicular screws must be used with Ø 5.5mm and Ø 6mm rods.

The K-ROD patient specific devices are available in Ø5.5 and Ø6mm.

8. Reason for Submission

The reason for this pre-market notification is the extension of the range of the KHEIRON® Spinal Fixation System (K201659) with patient specifically bent rods K-ROD. Those rods are bent by SMAIO before the surgery.

9. 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 implants are indicated as an adjunct to fusion to treat progresive spinal deformities (i.e. scoliosis, kyphosis, or lordosis) including idiopathic scoliosis, neuromuscular scoliosos, 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.

10. Substantial Equivalence

The K-ROD as part of the KHEIRON Spinal Fixation System is substantially equivalent to the predicate devices in terms of intended use, design, manufacturing materials, principles of operation, and technical characteristics and raises no new issues of safety or effectiveness.

11. Summary of the Technological Characteristics Compared to Predicate

Intended Use

The K-ROD used in association with KHEIRON Spinal Fixation System, and the predicates are intended to help provide immobilization and stabilization of spinal segments as an adjunct to fusion of the thoracic, lumbar, and/or sacral spine.

Materials

The K-ROD uses the same material as the predicates.

Design

The K-ROD and the predicates are equivalent in terms of shape and function.

Dimensions

The K-ROD and the predicates are equivalent in their dimensions.

Strength

The K-ROD has greater or equivalent strength values compared to the predicates.

12. Non-clinical Test Summary

The following tests were performed in support of this Special 510(k):

- 3-point flexion comparison between 90° rods bent with different rod bending processed (KHEIRON curved rod versus K-ROD);
- Dynamic axial compression bending and static torsion per ASTM F1717 (K-ROD versus PASS LP patient specific rod comparison);
- Literature review to support the addition of the patient-specific K-ROD.

The testing showed that the K-ROD met or exceeded acceptance criteria.

13. Clinical Test Summary

No clinical studies were performed.

14. Conclusions: Non-clinical and Clinical

S.M.A.I.O considers the K-ROD to be equivalent to the predicate devices listed above. This conclusion is based upon the devices' similarities in principles of operation, technology, materials, and indications for use.