October 5, 2020

S.M.A.I.O.
% J.D. Webb
Official Correspondent
The OrthoMedix Group, Inc.
4313 W. 3800 S.
West Haven, Utah 84401

Re: K201659
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: August 26, 2020
Received: August 28, 2020

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,

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)*

K201659

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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*5*10(k) Summary: KHEIRON® Spinal Fixation System

In accordance with 21 CFR 807.92 of the Federal Code of Regulations

Date Prepared	August 26, 2020
Submitted By	S.M.A.I.O. 2, Place Berthe Morisot – Parc Technologique 69800 SAINT-PRIEST FRANCE + 33 (0) 4 69 84 28 02 Tele
Primary Contact	J.D. Webb 4313 W. 3800 S West Haven, UT 84401 512-590-5810 Tele e-mail: jdwebb@orthomedix.net
Trade Name	KHEIRON® Spinal Fixation System
Common Name	Thoracolumbosacral Pedicle Screw System
Classification Name	Thoracolumbosacral Pedicle Screw System
Class	II
Product Code	NKB
CFR Section	21 CFR section 888.3070
Device Panel	Orthopedic
Primary Predicate Device	COLORADO 2™ Spinal System, Medtronic Sofarnor Danek (K020247)
Reference Predicate Devices	Revere® / CREO™ Stabilization System, Globus Medical (K143633 / K124058 / K113395) Synergy VLS – open, Cross Medical (K940631 / K950099) PWB (now Synergy), Cross Medical (K920116) Moss Miami SS, DePuy Spine (K000536) Moss Miami Ti, DePuy Spine (K955348) Rogozinski Thoracolumbar Spinal Rod, SMITH & NEPHEW (K954696)
Device Description	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 pedicle screw offers an excellent means of stabilizing a specific spinal segment. KHEIRON Spinal Fixation System includes screws 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.
Materials	Ti-6Al-4V ELI per ASTM F136
Intended Use	The KHEIRON Fixation System is a spinal fixation system intended to help provide immobilization and stabilization of spinal segments as an adjunct to fusion of the thoracic, lumbar, and/or sacral spine.

Substantial Equivalence Claimed to Predicate Devices	The KHEIRON Fixation System is substantially equivalent to the predicate devices in terms of intended use, design, materials used, mechanical safety and performances.
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.
Summary of the technological characteristics compared to predicate	<u>Intended Use</u> The KHEIRON Spinal Fixation System and the predicate devices are all intended to be used to maintain adequate disc space until fusion occurs. <u>Indications for Use</u> All of the devices comply with the indications for use specified in 21 CFR section 888.3070 for thoracolumbosacral pedicle screw systems. <u>Material</u> The KHEIRON Spinal Fixation System uses the same material as the predicates. <u>Design</u> The KHEIRON Spinal Fixation System and the predicates are equivalent in terms of shape, sizes, material, and manufacturing process. <u>Strength</u> The KHEIRON Spinal Fixation System has greater or equivalent strength values compared to other devices cleared for use in the thoracolumbosacral spine.
Non-clinical Test Summary	Static and dynamic compression bending and static torsion (ASTM F1717) and torsional and axial gripping capacity (ASTM F1798) was performed. The results of these evaluations indicate that the KHEIRON Spinal Fixation System is substantially equivalent to legally marketed predicate devices.
Clinical Test Summary	No clinical studies were performed
Conclusions: Non-clinical and Clinical	S.M.A.I.O. considers the KHEIRON Spinal Fixation System to be substantially equivalent to the legally marketed predicate devices listed above.