April 2, 2020

Astura Medical, LLC
Mr. Parker Kelch
Quality Manager
3168 Lionshead Ave, Suite 100
Carlsbad, California 92010

Re: K192006
Trade/Device Name: SIRION Lateral Lumbar Interbody Fusion System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: MAX, OVD, KWQ
Dated: March 5, 2020
Received: March 5, 2020

Dear Mr. Kelch:

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,

Brent L. Showalter, Ph.D.
Assistant Director (Acting)
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)*

K192006

Device Name
SIRION Lateral Lumbar Interbody Fusion System

Indications for Use *(Describe)*

The SIRION Lateral Lumbar Interbody System Spacer, either used individually or assembled to the SIRION plate, is indicated for intervertebral body fusion procedures in skeletally mature patients with degenerative disc disease (DDD) of the lumbar spine at one or two contiguous levels from L1-L2 to L5-S1. DDD is defined as discogenic pain with degeneration of the disc confirmed by history and radiographic studies. These DDD patients may also have up to Grade I spondylolisthesis or retrolisthesis at the involved level(s). SIRION Spacers are to be used with autogenous bone graft and supplemental fixation. Approved supplemental fixation includes the Olympic Posterior Spinal Fixation System. Patients should have at least six (6) months of non-operative treatment prior to treatment with an intervertebral cage.

The SIRION Lateral Lumbar Interbody System Plate, in 2-hole and 4-hole configurations, is indicated for use via a lateral or anterolateral surgical approach above the bifurcation of the great vessels in the treatment of thoracic and thoracolumbar (T1-L5) spine instability or via the anterior surgical approach, below the bifurcation of the great vessels in the treatment of lumbar and lumbosacral (L1-S1) spine instability as a result of: fracture (including dislocation and subluxation), tumor, degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies), scoliosis, kyphosis, lordosis, spinal stenosis, or a failed previous spine surgery.

The SIRION Lateral Lumbar Interbody System Plate, 1-hole buttress configuration is intended for use in conjunction with traditional supplemental fixation to maintain the relative position of interbody spacers during spinal fusion. The 1-hole plate is not intended for use in load-bearing applications

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.

510(k) Summary: SIRION Lateral Lumbar Interbody Fusion

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

Date Prepared	March 31, 2020
Submitted By	Astura Medical 3186 Lionshead Ave, Suite 100 Carlsbad, CA 92010 Phone: 760-814-8047
Contact	Parker Kelch 3186 Lionshead Ave, Suite 100 Carlsbad, CA 92010 Phone: 760-814-8047 x413 Email: quality@asturamedical.com
Trade Name	SIRION Lateral Lumbar Interbody Fusion System
Common Name	Intervertebral body fusion device
Classification Name	Intervertebral body fusion device – lumbar
Class	II
Product Code	MAX, OVD, KWQ
CFR Section	21 CFR section 888.3080 21 CFR section 888.3060
Device Panel	Orthopedic
Primary Predicate Device	HALF DOME Posterior Lumbar Interbody System (K152512)
Additional Predicate Device(s)	Half Dome (K163481, K172947, K182877) Biomet Fusion System (K141791, K163543); Alphatec Spine ATEC ALIF and LLIF Spacer System (K182746) NuVasive Decade Lateral Plate System (K130868) Genesys Spine Anterior Buttress Plate System (K133911)
Device Description	The Sirion Lateral Lumbar Interbody devices are implants developed for the substitution of the classical autogenous bone graft blocks. The cages assist to avoid complications related to the bone graft donation site (chronic pain, hematoma, infection, bone removal from the donor site making it impossible to remove bone again, quality of the iliac bone, accessing a healthy donor site that may become an unhealthy site, hernias by the incision). They are available in a range of footprints and heights to suit the individual pathology and anatomical conditions of the patient. The implants have a hollow center to allow placement of autogenous bone graft. The superior and inferior surfaces are open to promote contact of the bone graft with the vertebral end plates, allowing bone growth (arthrodesis). The Sirion spacer may also be used with an integrated plate component. The Sirion cages are designed to be used in conjunction with supplemental spinal fixation instrumentation.
Materials	PEEK-OPTIMA LT120HA (PEEK-OPTIMA HA Enhanced) – MAF 2227 Tantalum per ASTM F560 Titanium Alloy (Ti6-AL4-V ELI) per ASTM F136

	Nitinol #1 (ASTM F2063)
Substantial Equivalence Claimed to Predicate Devices	The Sirion Lateral Lumbar Interbody System is substantially equivalent to the predicate devices in terms of intended use, design, materials used, mechanical safety and performances.
Indications for Use	The SIRION Lateral Lumbar Interbody System Spacer, either used individually or assembled to the SIRION plate, is indicated for intervertebral body fusion procedures in skeletally mature patients with degenerative disc disease (DDD) of the lumbar spine at one or two contiguous levels from L1-L2 to L5-S1. DDD is defined as discogenic pain with degeneration of the disc confirmed by history and radiographic studies. These DDD patients may also have up to Grade I spondylolisthesis or retrolisthesis at the involved level(s). SIRION Spacers are to be used with autogenous bone graft and supplemental fixation. Approved supplemental fixation includes the Olympic Posterior Spinal Fixation System. Patients should have at least six (6) months of non-operative treatment prior to treatment with an intervertebral cage. The SIRION Lateral Lumbar Interbody System Plate, in 2-hole and 4-hole configurations, is indicated for use via a lateral or anterolateral surgical approach above the bifurcation of the great vessels in the treatment of thoracic and thoracolumbar (T1-L5) spine instability or via the anterior surgical approach, below the bifurcation of the great vessels in the treatment of lumbar and lumbosacral (L1-S1) spine instability as a result of: fracture (including dislocation and subluxation), tumor, degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies), scoliosis, kyphosis, lordosis, spinal stenosis, or a failed previous spine surgery. The SIRION Lateral Lumbar Interbody System Plate, 1-hole buttress configuration is intended for use in conjunction with traditional supplemental fixation to maintain the relative position of interbody spacers during spinal fusion. The 1-hole plate is not intended for use in load-bearing applications
Non-clinical Test Summary	The following analyses were conducted: • FEA • Static Compression Bending (ASTM F1717) • Dynamic Compression Bending (ASTM F1717) • Static Torsion (ASTM F1717) • Static Cantilever Bending Testing • Spacer and Plate Dissociation Testing The results of these evaluations indicate that the Sirion implants are equivalent to predicate devices.
Clinical Test Summary	No clinical studies were performed
Conclusions: Non-Clinical and Clinical	Astura Medical considers the Sirion Lateral Lumbar Interbody System to be substantially 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.