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

Re: K181139
Trade/Device Name: OLYMPIC Posterior Spinal Fixation System
Regulation Number: 21 CFR 888.3070
Regulation Name: Thoracolumbosacral Pedicle Screw Systems
Regulatory Class: Class II
Product Code: NKB, KWP
Dated: April 27, 2018
Received: April 30, 2018

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820);

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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/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 -S for MNM

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
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)*
K181139

Device Name
OLYMPIC Posterior Spinal Fixation System

Indications for Use *(Describe)*
The OLYMPIC Posterior 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 (T1-S2/Ilium): degenerative spondylolisthesis with objective evidence of neurological impairment, fracture, dislocation, deformities or curvatures (i.e. scoliosis, kyphosis, and/or lordosis), spinal tumor, and failed previous fusion (pseudarthrosis). When used as an adjunct to fusion, the OLYMPIC Posterior Spinal Fixation System is intended to be used with autograft/allograft.

In addition, the OLYMPIC Posterior Spinal Fixation System is intended for treatment of severe spondylolisthesis (grades 3 and 4) of the L5-S1 vertebra in skeletally mature patients receiving fusion by autogenous bone graft, having implants attached to the lumbosacral spine and/or ilium with removal of the implants after the attainment of a solid fusion. Levels of pedicle and non-pedicle fixation for these patients are L3-sacrum/ilium.

When used for posterior non-cervical pedicle and non-pedicle fixation in pediatric patients, the OLYMPIC Posterior Spinal Fixation System is intended to be used with autograft and/or allograft. Pediatric pedicle and non-pedicle 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: OLYMPIC Posterior Spinal Fixation System

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

Date Prepared	April 27, 2018
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	OLYMPIC Posterior Spinal Fixation System
Common Name	Posterior spinal fixation system
Classification Name	Thoracolumbosacral pedicle screw system Spinal interlaminal fixation orthosis
Class	II
Product Code	NKB KWP
CFR Section	21 CFR section 888.3070 21 CFR section 888.3050
Device Panel	Orthopedic
Primary Predicate Device	OLYMPIC PSFS (K153446)
Secondary Predicate Device(s)	Revere®/CREO™ Stabilization System - Globus Medical (K143633 / K124058 / K113395) Xia Spinal System - Stryker (K142381 /K113666 / K071373 / K060748) Expedium/Viper - DePuy Spine (K111136 / K131802) Universal Spinal System / Matrix - Synthes (K111358 / K100952) Moss Miami SS - DePuy Spine (K000536, K955348) Synergy VLS – open - Cross Medical (K940631 / K950099) PWB (now Synergy) - Cross Medical (K920116) CD HORIZON LEGACY – Medtronic (K090390 / K162494 / K162379)
Device Description	The OLYMPIC PSFS is a top loading thoracolumbar, sacral, and iliac fixation system implanted from the posterior approach and designed to provide fixation during the fusion process. The system is composed of preassembled uniplanar screws, hooks, rods, crosslinks, and rod connectors. The system is supported by a comprehensive set of instruments to install the implants within the system.

Materials	Ti-6Al-4V ELI (ASTM F136) CP Titanium Grade 4 (ASTM F67) Nitinol #1 (ASTM F2063) SS 17-4 (ASTM A564) SS 420 (ASTM A240)
Substantial Equivalence Claimed to Predicate Devices	The OLYMPIC PSFS is substantially equivalent to the predicate devices in terms of intended use, design, materials used, mechanical safety and performances.
Indications for Use	The OLYMPIC Posterior 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 (T1-S2/Ilium): degenerative spondylolisthesis with objective evidence of neurological impairment, fracture, dislocation, deformities or curvatures (i.e. scoliosis, kyphosis, and/or lordosis), spinal tumor, and failed previous fusion (pseudarthrosis). When used as an adjunct to fusion, the OLYMPIC Posterior Spinal Fixation System is intended to be used with autograft/allograft. In addition, the OLYMPIC Posterior Spinal Fixation System is intended for treatment of severe spondylolisthesis (grades 3 and 4) of the L5-S1 vertebra in skeletally mature patients receiving fusion by autogenous bone graft, having implants attached to the lumbosacral spine and/or ilium with removal of the implants after the attainment of a solid fusion. Levels of pedicle and non-pedicle fixation for these patients are L3-sacrum/ilium. When used for posterior non-cervical pedicle and non-pedicle fixation in pediatric patients, the OLYMPIC Posterior Spinal Fixation System is intended to be used with autograft and/or allograft. Pediatric pedicle and non-pedicle fixation is limited to a posterior approach.
Non-clinical Test Summary	The system was analyzed through Dynamic Compression Bending – ASTM F1717. The results of these evaluations indicate that the OLYMPIC PSFS is equivalent to predicate devices.
Clinical Test Summary	No clinical studies were performed.
Conclusions: Non-Clinical and Clinical	Astura Medical considers OLYMPIC PSFS 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