



Food and Drug Administration
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Astura Medical, LLC
% Mr. J.D. Webb
Authorized Contact Person
The OrthoMedix Group, Incorporated
1001 Oakwood Boulevard
Round Rock, Texas 78681

April 8, 2016

Re: K153446
Trade/Device Name: OLYMPIC Posterior Spinal Fixation System
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle screw spinal system
Regulatory Class: Class II
Product Code: OSH, MNI, MNH
Dated: March 9, 2016
Received: March 10, 2016

Dear Mr. 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. 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 Parts 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K153446

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 screw fixation for these patients are L3-sacrum/ilium.

When used for posterior non-cervical pedicle screw fixation in pediatric patients, the OLYMPIC Posterior Spinal Fixation System implants are indicated as an adjunct to fusion to treat adolescent idiopathic scoliosis. The OLYMPIC Posterior Spinal Fixation 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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) (Signature)

510(k) Summary: OLYMPIC Posterior Spinal Fixation System

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

Date Prepared	April 5, 2016
Submitted By	Astura Medical, LLC 5670 El Camino Real, Suite B Carlsbad, CA 92008 760-814-8047 Tele
Contact	J.D. Webb 1001 Oakwood Blvd Round Rock, TX 78681 512-388-0199 Tele 512-692-3699 Fax e-mail: jdwebb@orthomedix.net
Trade Name	OLYMPIC Posterior Spinal Fixation System
Common Name	pedicle screw system
Classification Name	Pedicle screw spinal system
Class	II
Product Code	OSH - Pedicle Screw Spinal System, Adolescent Idiopathic Scoliosis MNI - Orthosis, Spinal Pedicle Fixation MNH - Orthosis, Spondylolisthesis Spinal Fixation
CFR Section	21 CFR section 888.3070
Device Panel	Orthopedic
Primary Predicate Device	Revere®/CREO™ Stabilization System - Globus Medical (K143633)
Secondary Predicate Devices	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), Ti-6Al-4V (K955348) Synergy VLS – open - Cross Medical (K940631 / K950099) PWB (now Synergy) - Cross Medical (K920116) Polyaxial LP - Scient'x (K062912) Vectra System - Synthes (K050451) VERTEX Reconstruction System - Medtronic (K093434)
Device Description	The OLYMPIC Posterior Spinal Fixation System 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 polyaxial screws, monoaxial screws, 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 F37) CoCr alloy (ASTM F1537) Elgiloy CoCrNi alloy (ASTM F1058) Nitinol #1 (ASTM F2063)
Substantial Equivalence Claimed to Predicate Devices	The OLYMPIC Posterior Spinal Fixation System is substantially equivalent to the predicate devices in terms of intended use, design, materials used, mechanical safety and performances.

<p>Indications for Use</p>	<p>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.</p> <p>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 screw fixation for these patients are L3-sacrum/ilium.</p> <p>When used for posterior non-cervical pedicle screw fixation in pediatric patients, the OLYMPIC Posterior Spinal Fixation System implants are indicated as an adjunct to fusion to treat adolescent idiopathic scoliosis. The OLYMPIC Posterior Spinal Fixation System is intended to be used with autograft and/or allograft. Pediatric pedicle screw fixation is limited to a posterior approach.</p>
<p>Non-clinical Test Summary</p>	<p>The following analyses were conducted:</p> <ul style="list-style-type: none"> • Finite Element Analysis to determine worst case for testing • Static Compression Bending - ASTM F1717 • Dynamic Compression Bending - ASTM F1717 • Static Torsion - ASTM F1717 • Axial grip - ASTM F1798 • Torsional grip - ASTM F1798 • Corrosion testing - ASTM F2129 <p>The results of these evaluations indicate that the OLYMPIC Posterior Spinal Fixation System is equivalent to the predicate devices.</p>
<p>Clinical Test Summary</p>	<p>No clinical studies were performed</p>
<p>Conclusions: Non-clinical and Clinical</p>	<p>Astura Medical considers OLYMPIC Posterior Spinal Fixation System 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</p>