May 4, 2023

Astura Medical
Parker Kelch
Quality Manager
4949 W Royal Ln.
Irving, Texas 75063

Re: K222097
Trade/Device Name: OLYMPIC Deformity Band System
Regulation Number: 21 CFR 888.3010
Regulation Name: Bone Fixation Cerclage
Regulatory Class: Class II
Product Code: OWI, NKB, KWP, OLO
Dated: April 4, 2023
Received: April 4, 2023

Dear Parker 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,

Colin O'neill -S

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: 06/30/2023
*See PRA Statement below.*

510(k) Number *(if known)*
K222097

Device Name
OLYMPIC Deformity Band System

Indications for Use *(Describe)*
The OLYMPIC Deformity Band System is a temporary implant for use in orthopedic surgery. The band system is intended to provide temporary stabilization as a bone anchor during the development of solid bony fusion and aid in the repair of bone fractures. The indications for use include the following applications:

-Spinal trauma surgery, used in sublaminar or facet wiring techniques.

-Spinal reconstructive surgery, incorporated into constructs for the purpose of correction of spinal deformities such as idiopathic and neuromuscular scoliosis in patients 8 years of age or older, adult scoliosis, kyphosis and spondylolisthesis.

-Spinal degenerative surgery, as an adjunct to spinal fusions.

The OLYMPIC Deformity Band System may also be used in conjunction with other medical grade implants made of similar metals whenever "wiring" may help secure the attachment of the other implants.

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.**

This section applies only to requirements of the Paperwork Reduction Act of 1995.

***DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.***

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
*PRAStaff@fda.hhs.gov*

*"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."*

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

# Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
*See PRA Statement below.*

510(k) Number *(if known)*
K222097

Device Name
OLYMPIC Posterior Spinal Fixation System

Indications for Use *(Describe)*
The Olympic Posterior Spinal Fixation System is intended for immobilization and stabilization of the posterior, non-cervical spine in skeletally mature patients as an adjunct to fusion for the following indications: degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, trauma (i.e., fracture or dislocation), spinal stenosis, curvatures (i.e., scoliosis, kyphosis, or lordosis), tumor, pseudoarthrosis, and/or failed previous fusion.

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.

The OLYMPIC NAVIGATED INSTRUMENTS are intended to be used in the preparation and placement of OLYMPIC PSFS screws during spinal surgery to assist the surgeon in precisely locating anatomical structures in either open or minimally invasive procedures. These instruments are designed for use with the Medtronic StealthStation® System, which is indicated for any medical condition in which the use of stereotactic surgery may be appropriate, and where reference to a rigid anatomical structure, such as a skull, a long bone, or vertebra, can be identified relative to a CT or MR based model, fluoroscopy images, or digitized landmarks of the anatomy. Refer to the Astura Navigated Instrument system Instructions For Use (INS-00006) regarding the use of these instruments.

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)

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**510(k) Summary: OLYMPIC Deformity Band System**

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

| | | |
|---|---|---|
| Date Prepared | September 2, 2022 | |
| Submitted By | Astura Medical<br>4949 W Royal Ln.<br>Irving, TX<br>75063 | |
| Contact | Parker Kelch<br>Phone: 469-501-5530<br>Email: parker@asturamedical.com | |
| Trade Name | **OLYMPIC Deformity Band System** | **OLYMPIC Posterior Spinal Fixation System** |
| Common Name | Bone fixation cerclage | Posterior pedicle screw |
| Classification Name | Bone Fixation Cerclage, Sublaminar | Thoracolumbosacral Pedicle Screw System<br>Appliance, Fixation, Spinal Interlaminal<br>Orthopedic Stereotaxic Instrument |
| Class | II | II |
| Product Code | OWI | NKB, KWP, OLO |
| CFR Section | 21 CFR section 888.3010 | 21 CFR sections 888.3070, 888.3050, 882.4560 |
| Device Panel | Orthopedic | Orthopedic |
| Primary Predicate Device | Zimmer Universal Clamp Spinal Fixation System (K142053) | OLYMPIC Posterior Spinal Fixation System (K181139) |
| Additional Predicate Device(s) | JAZZ System, Including JAZZ Band (K170730)<br>Medicrea International S.A. LigaPASS (K173506) | Spinal USA ReForm Pedicle Screw System (K131343)<br>OLYMPIC Navigated Instruments (K172166; Reference Device) |
| Device Description | The OLYMPIC Deformity Band System is a system designed to stabilize a vertebrae during the fusion process. The system is composed of sublaminar bad cerclages and band connectors. The system is supported by a comprehensive set of instruments to install the implants within the system. All implant components are manufactured from the materials listed in the table below. | The OLYMPIC Posterior Spinal Fixation System is a top loading thoracolumbar, sacral, and iliac fixation system designed to provide fixation during the fusion process. The system is composed of preassembled polyaxial screws, monoaxial screws, rods, cross connectors, rod connectors. The system is supported by a comprehensive set of instruments to install the implants within the system. All implant components are manufactured from the materials listed in the table below. |
| Materials | PET (ISO 10993)<br>Stainless Steel (ISO 9445-1, EN 10088-2)<br>Stainless Steel 17-4 (ASTM A564)<br>Stainless Steel 465 (ASTM A546)<br>Stainless Steel 316 (ASTM A240)<br>Ti-6Al-4V ELI (ASTM F136) | Stainless Steel (ISO 9445-1, EN 10088-2)<br>Stainless Steel 17-4 (ASTM A564)<br>Stainless Steel 465 (ASTM A546)<br>Stainless Steel 316 (ASTM A240)<br>Ti-6Al-4V ELI (ASTM F136)<br>Tantalum (ASTM F560)<br>Nitinol #1 (ASTM F2063) |

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| Substantial Equivalence Claimed to Predicate Devices | The OLYMPIC Deformity Band System is substantially equivalent to the predicate devices in terms of intended use, design, materials used, mechanical safety and performances. | N/A |
| Indications for Use | The OLYMPIC Deformity Band System is a temporary implant for use in orthopedic surgery. The band system is intended to provide temporary stabilization as a bone anchor during the development of solid bony fusion and aid in the repair of bone fractures. The indications for use include the following applications:<br><br>-Spinal trauma surgery, used in sublaminar or facet wiring techniques.<br><br>-Spinal reconstructive surgery, incorporated into constructs for the purpose of correction of spinal deformities such as idiopathic and neuromuscular scoliosis in patients 8 years of age or older, adult scoliosis, kyphosis and spondylolisthesis.<br><br>-Spinal degenerative surgery, as an adjunct to spinal fusions.<br><br>The OLYMPIC Deformity Band System may also be used in conjunction with other medical grade implants made of similar metals whenever "wiring" may help secure the attachment of the other implants. | The Olympic Posterior Spinal Fixation System is intended for immobilization and stabilization of the posterior, non-cervical spine in skeletally mature patients as an adjunct to fusion for the following indications: degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, trauma (i.e., fracture or dislocation), spinal stenosis, curvatures (i.e., scoliosis, kyphosis, or lordosis), tumor, pseudoarthrosis, and/or failed previous fusion.<br><br>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.<br><br>The OLYMPIC NAVIGATED INSTRUMENTS are intended to be used in the preparation and placement of OLYMPIC PSFS screws during spinal surgery to assist the surgeon in precisely locating anatomical structures in either open or minimally invasive procedures. These instruments are designed for use with the Medtronic StealthStation® System, which is indicated for any medical condition in which the use of stereotactic surgery may be appropriate, and where reference to a rigid anatomical structure, such as a skull, a long bone, or vertebra, can be identified relative to a CT or MR based model, fluoroscopy images, or digitized landmarks of the anatomy. Refer to the Astura Navigated Instrument system Instructions For Use (INS-00006) regarding the use of these instruments. |
| Non-clinical Test Summary | The following analyses were conducted:<br>• Rotational Grip Testing – ASTM F1798<br>• Axial Grip Testing – ASTM F1798 | N/A |

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| | • Dynamic Tension – ASTM F1798<br>• Static Tension – ASTM F1798<br>The results of these evaluations indicate that the OLYMPIC PSDS is equivalent to the predicate devices. | |
| Clinical Test Summary | No clinical studies were performed. | N/A |
| Conclusions: Non-Clinical and Clinical | Astura Medical considers OLYMPIC Deformity Band 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 | N/A |