



October 21, 2025

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

Re: K252346

Trade/Device Name: OLYMPIC Posterior Spinal Fixation System; MASADA Modular Spinal Fixation System

Regulation Number: 21 CFR 888.3070

Regulation Name: Thoracolumbosacral pedicle screw system

Regulatory Class: Class II

Product Code: NKB, KWP, OLO, OUR

Dated: September 19, 2025

Received: September 19, 2025

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (<https://www.fda.gov/media/99812/download>) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (<https://www.fda.gov/media/99785/download>).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at <https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system>.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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](mailto: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

# Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.

K252346

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Please provide the device trade name(s).

?

OLYMPIC Posterior Spinal Fixation System;  
MASADA Modular Spinal Fixation System

Please provide your Indications for Use below.

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**Pedicle Screw System:** 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.

**Sublaminar Band System:** 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.

**S2AI Screws:** The OLYMPIC Posterior Spinal Fixation System S2AI Screw System is intended for sacroiliac joint fusion for the following conditions:

- Sacroiliac joint dysfunction that is a direct result of sacroiliac joint disruption and degenerative sacroiliitis. This includes conditions whose symptoms began during pregnancy or in the peripartum period and have persisted postpartum for more than 6 months.
- To augment immobilization and stabilization of the sacroiliac joint in skeletally mature patients undergoing sacropelvic fixation as part of a lumbar or thoracolumbar fusion.
- Acute, non-acute, and non-traumatic fractures involving the sacroiliac joint.

When connected to OLYMPIC posterior rods the OLYMPIC S2AI Screw System is intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to thoracolumbosacral fusion for the following acute and chronic instabilities or deformities of the thoracic, lumbar, and sacral spine:

- Degenerative disc disease (DDD) as defined by back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies
- Spondylolisthesis
- Trauma (i.e., fracture or dislocation)
- Spinal stenosis
- Deformities or curvatures (i.e., scoliosis, kypohosis, and/or lordosis)

- Spinal tumor
- Pseudarthrosis
- Failed previous fusion

Navigated Instrument System: 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.

Pedicle Screw System: The MASADA Modular 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 MASADA pedicle screw implants are indicated as an adjunct to fusion to treat adolescent idiopathic scoliosis. The MASADA pedicle screw is intended to be used with autograft and/or allograft. Pediatric pedicle screw fixation is limited to a posterior approach.

Sublaminar Band System: The MASADA sublaminar band 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 MASADA sublaminar band 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.

S2AI Screws: The MASADA Modular Spinal Fixation System S2AI Screw System is intended for sacroiliac joint fusion for the following conditions:

- Sacroiliac joint dysfunction that is a direct result of sacroiliac joint disruption and degenerative sacroiliitis. This includes conditions whose symptoms began during pregnancy or in the peripartum period and have persisted postpartum for more than 6 months.
- To augment immobilization and stabilization of the sacroiliac joint in skeletally mature patients undergoing sacropelvic fixation as part of a lumbar or thoracolumbar fusion.
- Acute, non-acute, and non-traumatic fractures involving the sacroiliac joint.

When connected to MASADA posterior rods the MASADA S2AI Screw System is intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to thoracolumbosacral fusion for the following acute and chronic instabilities or deformities of the thoracic, lumbar, and sacral spine:

- Degenerative disc disease (DDD) as defined by back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies
- Spondylolisthesis
- Trauma (i.e., fracture or dislocation)

- Spinal stenosis
- Deformities or curvatures (i.e., scoliosis, kypohosis, and/or lordosis)
- Spinal tumor
- Pseudarthrosis
- Failed previous fusion

Navigated Instrument System: The MASADA navigated instruments are intended to be used in the preparation and placement of MASADA 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.

Please select the types of uses (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: S2AI Implants**  
**OLYMPIC Posterior Spinal Fixation System**  
**MASADA Modular Spinal Fixation System**

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

Date Prepared	June 16, 2025
Submitted By	Astura Medical 4949 W Royal Ln. Irving, TX 75063 Phone: 469-501-5530
Contact	Parker Kelch Phone: 469-501-5530 x503 Email: parker@asturamedical.com
Trade Name	MASADA Modular Spinal Fixation System
Common Name	Posterior spinal fixation system
Classification Name	Thoracolumbosacral pedicle screw system Spinal interlaminar fixation orthosis Orthopedic stereotaxic instrument
Class	II
Product Code	NKB
	KWP, OLO, OUR
CFR Section	21 CFR section 888.3070, 888.3050, 888.3010, 882.4560
Device Panel	Orthopedic
Primary Predicate Device	MASADA Modular Spinal Fixation System (K231694)
Additional Predicate Device(s)	OLYMPIC (K182239) SI-Bone (K222774) Reunion (K232211)
Device Description	<p>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, and hooks. The system is supported by a comprehensive set of instruments to install the implants within the system.</p> <p>The MASADA Modular Spinal Fixation System S2AI Screw System consist of an assortment of implants in various lengths and diameters, and associated instrument sets for both Open and minimally invasive (MIS) approaches. The S2AI bone screw implant component made from Titanium alloy (Ti-6Al-4V-ELI) as described by ASTM F136. It is intended to provide sacroiliac joint fusion in the sacral alar iliac (SAI) trajectory (when used with commercially available sacroiliac joint fusion promoting devices), and provide foundational stabilization when connected to pedicle screw fixation systems in both the SAI and the Iliac trajectories. Additionally, the MASADA S2AI Screw System can be placed into the S1 pedicle. It is designed for connection to the MASADA Pedicle Screw</p>

	System 5.5mm or 6.0mm diameter titanium alloy or cobalt chrome alloy spinal fixation rods.
Materials	Ti-6Al-4V ELI (ASTM F136) CP Titanium Grade 4 (ASTM F67) CoCrMo alloy (ASTM F1537) Elgiloy CoCrNi alloy (ASTM F1058) Nitinol #1 (ASTM F2063) PET (ISO 10993)
Substantial Equivalence Claimed to Predicate Devices	The addition of S2AI screws is substantially equivalent to the predicate systems in terms of intended use, design, materials used, mechanical safety and performances.
Indications for Use	<p><b>Pedicle Screw System:</b> 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.</p> <p><b>Sublaminar Band System:</b> 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:</p> <ul style="list-style-type: none"> <li>-Spinal trauma surgery, used in sublaminar or facet wiring techniques.</li> <li>-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.</li> <li>-Spinal degenerative surgery, as an adjunct to spinal fusions.</li> </ul> <p>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.</p> <p><b>S2AI Screws:</b> The OLYMPIC Posterior Spinal Fixation System S2AI Screw System is intended for sacroiliac joint fusion for the following conditions:</p> <ul style="list-style-type: none"> <li>• Sacroiliac joint dysfunction that is a direct result of sacroiliac joint disruption and degenerative sacroiliitis. This includes conditions whose</li> </ul>

symptoms began during pregnancy or in the peripartum period and have persisted postpartum for more than 6 months.

- To augment immobilization and stabilization of the sacroiliac joint in skeletally mature patients undergoing sacropelvic fixation as part of a lumbar or thoracolumbar fusion.

- Acute, non-acute, and non-traumatic fractures involving the sacroiliac joint.

When connected to OLYMPIC rods the OLYMPIC S2AI Screw System is intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to thoracolumbosacral fusion for the following acute and chronic instabilities or deformities of the thoracic, lumbar, and sacral spine:

- Degenerative disc disease (DDD) as defined by back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies

- Spondylolisthesis

- Trauma (i.e., fracture or dislocation)

- Spinal stenosis

- Deformities or curvatures (i.e., scoliosis, kyphosis, and/or lordosis)

- Spinal tumor

- Pseudarthrosis

- Failed previous fusion

The safety and effectiveness of this device has not been established when used in conjunction with bone cement or for use in patients with poor bone quality (e.g., osteoporosis, osteopenia).

**Navigated Instrument System:** 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.

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- Degenerative disc disease (DDD) as defined by back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies
- Spondylolisthesis

	<ul style="list-style-type: none"> <li>• Trauma (i.e., fracture or dislocation)</li> <li>• Spinal stenosis</li> <li>• Deformities or curvatures (i.e., scoliosis, kyphosis, and/or lordosis)</li> <li>• Spinal tumor</li> <li>• Pseudarthrosis</li> <li>• Failed previous fusion</li> </ul> <p>The safety and effectiveness of this device has not been established when used in conjunction with bone cement or for use in patients with poor bone quality (e.g., osteoporosis, osteopenia).</p> <p><b>Navigated Instrument System:</b> The MASADA navigated instruments are intended to be used in the preparation and placement of MASADA 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.</p>
<p>Non-clinical Test Summary</p>	<p>The following analyses were conducted:</p> <ul style="list-style-type: none"> <li>• Torsional Properties ASTM F543</li> <li>• Driving Torque ASTM F543</li> <li>• Axial Pullout Strength ASTM F543</li> <li>• Static Bending ASTM F2193</li> <li>• Dynamic Bending ASTM F2193</li> <li>• Pitting Corrosion ASTM F2129</li> </ul>
<p>Clinical Test Summary</p>	<p>No clinical studies were performed.</p>
<p>Conclusions: Non-Clinical and Clinical</p>	<p>Astura Medical considers the addition of S2AI implants to the OLYMPIC AND MASADA systems 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>