January 22, 2026

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

Re: K252885
Trade/Device Name: OLYMPIC Posterior Spinal Fixation System; MASADA Modular Spinal Fixation System
Regulation Number: 21 CFR 888.3027
Regulation Name: Polymethylmethacrylate (PMMA) bone cement
Regulatory Class: Class II
Product Code: PML, NKB, KWP, OLO, OWI
Dated: January 14, 2026
Received: January 14, 2026

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) 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.	K252885 ?

Please provide the device trade name(s). ?

OLYMPIC Posterior Spinal Fixation System;
MASADA Modular Spinal Fixation System

Please provide your Indications for Use below. ?

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.

Fenestrated Screw System: Fenestrated Screw System: When used in conjunction with the listed compatible bone cements the OLYMPIC Fenestrated spinal implants are intended to restore integrity of the spinal column even in the absence of fusion for a limited time period in patients with advanced stage tumors involving the thoracic and lumbar spine in whom life expectancy is of insufficient duration to permit achievement fusion. The OLYMPIC Fenestrated Screws augmented with the listed compatible bone cements are limited to use in spinal levels where the structural integrity of the spine is not severely compromised. Compatible bone cements include G21 V-STEADY, G21 V-FAST, Teknimed F20, and Teknimed HIGH V+.

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.

Fenestrated Screw System: Fenestrated Screw System: When used in conjunction with the listed compatible bone cements the OLYMPIC Fenestrated spinal implants are intended to restore integrity of the spinal column even in the absence of fusion for a limited time period in patients with advanced stage tumors involving the thoracic and lumbar spine in whom life expectancy is of insufficient duration to permit achievement fusion. The OLYMPIC Fenestrated Screws augmented with the listed compatible bone cements are limited to use in spinal levels where the structural integrity of the spine is not severely compromised. Compatible bone cements include G21 V-STEADY, G21 V-FAST, Teknimed F20, and Teknimed HIGH V+.

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)	?

510(k) Summary: Fenestrated Screws
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	December 18, 2025
Submitted By	Astura Medical 4949 W Royal Ln Irving, TX 75063
Contact	Parker Kelch 4949 W Royal Ln Irving, TX 75063 Phone: 469-501-5530 x503 Email: parker@asturamedical.com
Trade Name	OLYMPIC Posterior Spinal Fixation System; MASADA Modular Spinal Fixation System
Common Name	Posterior Spinal Fixation System
Classification Name	Polymethylmethacrylate (PMMA) bone cement Thoracolumboscral pedicle screw system Spinal interlaminal fixation orthosis Orthopedic stereotaxic instrument Bone fixation cerclage
Class	II
Product Code	PML, NKB, KWP, OLO, OWI
CFR Section	21 CFR Section 888.3027 21 CFR Section 888.3070 21 CFR Section 888.3050 21 CFR Section 882.4560 21 CFR Section 888.3010
Device Panel	Orthopedic
Primary Predicate Device	Meta+ Bone Cement & M.U.S.T. Fenestrated Pedicle Screw System (K241034)
Reference Devices	MASADA Modular Spinal Fixation System (K231694) OLYMPIC MIS (K182239) HIGH V+ (K161114) V-STEADY, V-FAST (K150408)
Device Description	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. The MASADA Modular 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 modular

	polyaxial screws, and rods. The system is supported by a comprehensive set of instruments to install the implants within the system for percutaneous and minimally invasive access. All implant components are manufactured from the materials listed in the table below.
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)
Substantial Equivalence Claimed to Predicate Devices	The MASADA System is substantially equivalent to the predicate devices in terms of intended use, design, materials used, mechanical safety and performance.
Indications for Use	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. **Fenestrated Screw System:** When used in conjunction with the listed compatible bone cements the OLYMPIC Fenestrated spinal implants are intended to restore integrity of the spinal column even in the absence of fusion for a limited time period in patients with advanced stage tumors involving the thoracic and lumbar spine in whom life expectancy is of insufficient duration to permit achievement fusion. The OLYMPIC Fenestrated Screws augmented with the listed compatible bone cements are limited to use in spinal levels where the structural integrity of the spine is not severely compromised. Compatible bone cements include the G21 V-STEADY, G21 V-FAST, Teknimed F20, and Teknimed HIGH V+. 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. **Fenestrated Screw System:** When used in conjunction with the listed compatible bone cements the MASADA Fenestrated spinal implants are intended to restore integrity of the spinal column even in the absence of fusion for a limited time period in patients with advanced stage tumors involving the thoracic and lumbar spine in whom life expectancy is of insufficient duration to permit achievement fusion. The MASADA Fenestrated Screws augmented with the listed compatible bone cements are limited to use in spinal levels where the structural integrity of the spine is not severely compromised. Compatible bone cements include the G21 V-STEADY, G21 V-FAST, Teknimed F20, and Teknimed HIGH V+. 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.

Non-clinical Test Summary	• ASTM F1717
	  ○ Static Compression Bending
	  ○ Dynamic Compression Bending
	  ○ Static Torsion
	• ASTM F543
	  ○ Torsional Yield
	  ○ Removal Toque
	  ○ Axial Pullout
	• Bone Cement Injection Testing

Clinical Test Summary	No clinical studies were performed.
Conclusions: Non-Clinical and Clinical	Astura Medical considers the addition of fenestrated screws to the OLYMPIC and MASADA systems 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.