April 4, 2025

DeGen Medical
℅ Justin Gracyalny
Regulatory Affairs Manager
Secure BioMed Evaluations
7828 Hickory Flat Hwy
Woodstock, Georgia 30188

Re: K250667
Trade/Device Name: DeGen Medical Patient Specific Implant (PSI) System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: MAX, OVD, PHM
Dated: March 5, 2025
Received: March 5, 2025

Dear Justin Gracyalny:

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 FDA for

Brent Showalter, Ph.D.
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

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

510(k) Number *(if known)*
K250667

Device Name
DeGen Medical Patient Specific Implant (PSI) System

Indications for Use *(Describe)*
Solar-S™ PSI (Anterior, Standalone, With Integrated Fixation) and Solar- A™ PSI Spacers (Anterior, Non-Standalone, With Integrated Fixation):

The Solar-S™ PSI (Standalone) and Solar-A™ PSI (Non-Standalone, With Integrated Fixation) are lumbar interbody fusion devices intended for use in patients with degenerative disc disease (DDD) of the lumbosacral spine (L1-S1). DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. In addition, these patients may have up to Grade 1 spondylolisthesis or retrolisthesis at the involved level(s). These patients should be skeletally mature and have had at least six (6) months of non-operative treatment. Solar-S™ PSI and Solar-A™ PSI Spacers are to be filled with autograft bone and/or allogenic bone graft composed of cancellous and/or corticocancellous bone.

Solar-S™ PSI Used with Screws or Tusks:
When used with three (3) screws, Solar-S™ PSI Spacers devices with a lordotic angle ≤20° can be used as standalone interbody fusion devices at 1 or 2 contiguous levels.

When used with three (3) tusks, interbody devices must always be used with supplemental fixation and may be used at one or more levels.

Hyperlordotic interbody devices (>20° lordosis) used with screws or tusks, must always be used with supplemental fixation, and may be used at one or more levels.

When used with supplemental fixation, all Solar-S™ PSI Spacers used with screws or tusks may be used at one or more levels.

Solar-A™ PSI:
These devices are intended to be used at one or more levels with supplemental fixation systems that have been cleared for use in the lumbosacral spine (e.g., posterior pedicle screw and rod systems, anterior plate systems, anterior screw and rod systems). Hyperlordotic interbody devices (≥20° lordosis) must be used with at least anterior supplemental fixation.

Solar-M™ PSI Spacers (Anterior, Without Integrated Fixation):
Solar-M™ PSI Spacers are lumbar interbody fusion devices indicated at one or more levels of the thoracic spine (T1-T12), thoracolumbar junction (T12-L1), or lumbosacral spine (L1-S1) as an adjunct to fusion in patients with the following indications: degenerative disc disease (DDD), disc herniation (with myelopathy and/or radiculopathy), spondylolisthesis, deformity (degenerative scoliosis or kyphosis), spinal stenosis, and failed previous fusion (pseudarthrosis). DDD is defined as discogenic back painwith degeneration of the disc confirmed by history and radiographic studies. These patients should be skeletally mature and have had at least six (6) months of non-operative treatment. Solar-M™ PSI Spacers are to be filled with autograft bone and/or allogenic bone graft composed of cancellous and/or corticocancellous bone. These devices are intended to be used with supplemental fixation systems that have been cleared for use in the thoracolumbosacral spine (e.g., posterior pedicle screw and rod systems, anterior plate systems, anterior screw and rod systems). Hyperlordotic interbody devices (≥20° lordosis) must be used with at least anterior supplemental fixation.

Impulse™ PSI Spacers (Posterior / Transforaminal):

The Impulse™ PSI is an intervertebral body fusion device intended for use in skeletally mature patients with Degenerative Disk Disease (DDD) of the lumbar spine with up to Grade 1 Spondylolisthesis at one or more levels from L1-S1. DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. The DeGen Medical Impulse™ PSI is indicated to be used with autograft and/or allograft comprised of cancellous and/or corticocancellous bone graft to facilitate fusion and are intended to be used with supplemental fixation systems cleared for use in the lumbar spine. The device is to be used in patients who have had six months of nonoperative treatment.

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.

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510(k) Summary of Safety and Effectiveness

Date	March 5, 2025
Sponsor	DeGen Medical 1321-C North Cashua Drive Florence, SC 29501 Phone 877-240-7838 Fax 843-407-0545
510(k) Contact	Secure BioMed Evaluations Justin Gracyalny, MSE 7828 Hickory Flat Highway, Suite 120 Woodstock, GA 30188 770-837-2681 Regulatory@SecureBME.com
Trade Name	DeGen Medical Patient-Specific Implant (PSI) System
Common Name	Intervertebral body fusion device
Code–Classification	MAX, OVD, PHM 21 CFR 888.3080 : Class II
Primary Predicate	K241077 DeGen Medical Patient-Specific Implant (PSI) System
Device Description	The DeGen Medical Patient-Specific Implant (PSI) System is a series of patient specific lumbar interbody spacers intended for use in anterior (Solar™ PSI) or posterior / transforaminal (Impulse™ PSI) lumbar fusion procedures. The Impulse™ PSI spacers are available in two configurations: Impulse™ PSI and Impulse™ Hyperlordotic PSI. The Solar™ PSI patient specific spacers are available in three configurations; Solar-S™ (integrated fixation), Solar-A™ (anterolateral, with integrated fixation), and Solar-M™ (monolithic, without integrated fixation). The Solar™ PSI implants incorporate integrated fixation in the form of screws manufactured from Ti-6AL-4V ELI titanium alloy per ASTM F136 or tusks additively manufactured from Puri-Ti™ unalloyed titanium. The Solar-S™ PSI spacers must be used with three (3) integrated screws and the spacer must have ≤20° of lordosis to be considered for standalone use. Impulse™ and Solar™ PSIs are additively manufactured from Puri-Ti™ unalloyed titanium. The Impulse™ and Solar™ PSIs are designed individually for each patient using patient imaging data (X-Ray, MRI, CT). Variable dimensions include anterior and posterior heights, bone graft window, lordosis, coronal angle, length, and width. When provided with an adequate CT scan, implants may also include patient-matched endplates. All implants are provided in their final geometry and are not intended to be altered or reshaped at the time of surgery.

Indications for Use	Solar-S™ PSI (Anterior, Standalone, With Integrated Fixation) and Solar-A™ PSI Spacers (Anterior, Non-Standalone, With Integrated Fixation) The Solar-S™ PSI (Standalone) and Solar-A™ PSI (Non-Standalone, With Integrated Fixation) are lumbar interbody fusion devices intended for use in patients with degenerative disc disease (DDD) of the lumbosacral spine (L1-S1). DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. In addition, these patients may have up to Grade 1 spondylolisthesis or retrolisthesis at the involved level(s). These patients should be skeletally mature and have had at least six (6) months of non-operative treatment. Solar-S™ PSI and Solar-A™ PSI Spacers are to be filled with autograft bone and/or allogenic bone graft composed of cancellous and/or corticocancellous bone. • Solar-S™ PSI Used with Screws or Tusks: When used with three (3) screws, Solar-S™ PSI Spacers devices with a lordotic angle ≤20° can be used as standalone interbody fusion devices at 1 or 2 contiguous levels. When used with three (3) tusks, interbody devices must always be used with supplemental fixation and may be used at one or more levels. Hyperlordotic interbody devices (>20° lordosis) used with screws or tusks, must always be used with supplemental fixation, and may be used at one or more levels. When used with supplemental fixation, all Solar-S™ PSI Spacers used with screws or tusks may be used at one or more levels. • Solar-A™ PSI: These devices are intended to be used at one or more levels with supplemental fixation systems that have been cleared for use in the lumbosacral spine (e.g., posterior pedicle screw and rod systems, anterior plate systems, anterior screw and rod systems). Hyperlordotic interbody devices (≥20° lordosis) must be used with at least anterior supplemental fixation. Solar-M™ PSI Spacers (Anterior, Without Integrated Fixation) Solar-M™ PSI Spacers are lumbar interbody fusion devices indicated at one or more levels of the thoracic spine (T1-T12), thoracolumbar junction (T12-L1), or lumbosacral spine (L1-S1) as an adjunct to fusion in patients with the following indications: degenerative disc disease (DDD), disc herniation (with myelopathy and/or radiculopathy), spondylolisthesis, deformity (degenerative scoliosis or kyphosis), spinal stenosis, and failed previous fusion (pseudarthrosis). DDD is defined as discogenic back pain

	with degeneration of the disc confirmed by history and radiographic studies. These patients should be skeletally mature and have had at least six (6) months of non-operative treatment. Solar-M™ PSI Spacers are to be filled with autograft bone and/or allogenic bone graft composed of cancellous and/or corticocancellous bone. These devices are intended to be used with supplemental fixation systems that have been cleared for use in the thoracolumbosacral spine (e.g., posterior pedicle screw and rod systems, anterior plate systems, anterior screw and rod systems). Hyperlordotic interbody devices (≥20° lordosis) must be used with at least anterior supplemental fixation. <u>Impulse™ PSI Spacers (Posterior / Transforaminal)</u> The Impulse™ PSI is an intervertebral body fusion device intended for use in skeletally mature patients with Degenerative Disk Disease (DDD) of the lumbar spine with up to Grade 1 Spondylolisthesis at one or more levels from L1-S1. DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. The DeGen Medical Impulse™ PSI is indicated to be used with autograft and/or allograft comprised of cancellous and/or corticocancellous bone graft to facilitate fusion and are intended to be used with supplemental fixation systems cleared for use in the lumbar spine. The device is to be used in patients who have had six months of nonoperative treatment.
Technological Characteristics	The subject is identical in intended use, indications for use, design, and function to the predicate device. The purpose of this submission was to add a non-sterile implant offering to the previously cleared sterile implant configuration. This submission also addressed minor changes in manufacturing flow to support the new configuration. In conclusion, the technological design features of the subject implants were compared to the predicates in intended use, indications for use, design, function and technology and it was demonstrated that they are substantially equivalent.

Performance Testing	The following testing was performed to support substantial equivalence of the subject device:
	• Steam Sterilization Validation per ISO 17665
	• Cleaning validation including evaluation of the following endpoints:
	  ○ Visual inspection for any residual contamination
	  ○ Total Organic Carbon per USP <643>
	  ○ Gravimetric quantitation of residual particulates following polar and non-polar extractions per ASTM F2459
	  ○ Bacterial Endotoxin Testing per USP <85> and AAMI ST72
	• Cytotoxicity Testing per ISO 10993-5
	
	The results of these studies show the subject DeGen Medical Patient-Specific Implant (PSI) System is substantially equivalent to the predicate device.

Conclusions	Based on the indications for use, technological characteristics, performance testing, and comparison to the predicate device, the subject DeGen Medical Patient-Specific Implant (PSI) System is as safe and as effective as the legally marketed predicate device.