June 16, 2023

DeGen Medical
% Justin Gracyalny, MSE
Regulatory Affairs Manager
Secure BioMed Evaluations
7828 Hickory Flat Highway Suite 120
Woodstock, Georgia 30188

Re: K231199
Trade/Device Name: Solar™ Lumbar Interbody Fusion System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: MAX, OVD, PHM
Dated: April 27, 2023
Received: April 27, 2023

Dear Mr. 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 (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,

Brent Showalter -S

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

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)*
K231199

Device Name
Solar™ Lumbar Interbody Fusion System

Indications for Use *(Describe)*
Solar-S™ (Standalone, With Integrated Fixation) and Solar-A™ (Non-Standalone, With Integrated Fixation)
The Solar-S™ (Standalone) and Solar-A™ (Non-Standalone) are lumbar interbody fusion devices intended for use in patients with degenerative disc disease (DDD) at one or two contiguous levels of the lumbosacral spine (L2-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™ and Solar-A™ ALIF Spacers are to be filled with autograft bone and/or allogenic bone graft composed of cancellous and/or corticocancellous bone.

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

Hyperlordotic interbody devices (>20° lordosis) used with screws, must always be used with supplemental fixation, and may be used at 1 or 2 levels.

• Solar-A™:
These devices are intended to be used 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™ ALIF Spacers (Without Integrated Fixation) Solar-M™ ALIF 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), spondylolilsthesis, 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 has at least six (6) months of non-operative treatment. Solar-M™ ALIF 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.

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.

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510(k) Summary of Safety and Effectiveness

Date	June 14, 2023
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 Linda Braddon, Ph.D. 7828 Hickory Flat Highway Suite 120 Woodstock, GA 30188 770-837-2681 Regulatory@SecureBME.com
Trade Name	Solar™ Lumbar Interbody Fusion System
Common Name	Intervertebral body fusion device
Code–Classification	MAX, OVD, PHM 21 CFR 888.3080 : Class II
Primary Predicate	K213935 Osseus Fusion Systems PISCES™-SA Standalone ALIF Interbody System
Additional Predicates	K191391, K222270 Globus Medical Inc. HEDRON™ Lumbar Spacers K081849 Blackstone Medical Pillar SA PEEK Spacer System K132790 Zimmer Spine InFix Anterior Lumbar System K210090, K223418 DeGen Medical Impulse AM™ Interbody Fusion System
Device Description	The Solar™ Lumbar Interbody Fusion System is a lumbar interbody fusion device for posterior and transforaminal lumbar fusion procedures. The Solar™ system includes various widths, depths, and heights. The Solar™ device is comprised of a single component that is additively manufactured. The superior and inferior endplates feature a porous surface to mitigate subsidence and expulsion. The standalone (Solar-S™), anterolateral (Solar-A™), and monolithic (Solar-M™) configurations feature an anterior face with threaded holes and slots to rigidly connect to an instrument for surgical insertion. Superior and inferior faces feature a central aperture to constrain bone graft. The DeGen Medical Solar™ spacers are additively manufactured from Puri-Ti™ unalloyed titanium. The Solar-S™ and Solar-A™ incorporate integrated fixation in the form of screws manufactured from Titanium-6AL-4V ELI Alloy per ASTM F136. The Solar-S™ Lumbar Interbody Spacer must be used with three (3) integrated screws and the spacer must have ≤20° of lordosis to be considered for standalone use.

510(k) Summary of Safety and Effectiveness

Indications for Use	Solar-S™ (Standalone, With Integrated Fixation) and Solar-A™ (Non-Standalone, With Integrated Fixation) The Solar-S™ (Standalone) and Solar-A™ (Non-Standalone) are lumbar interbody fusion devices intended for use in patients with degenerative disc disease (DDD) at one or two contiguous levels of the lumbosacral spine (L2-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™ and Solar-A™ ALIF Spacers are to be filled with autograft bone and/or allogenic bone graft composed of cancellous and/or corticocancellous bone. • Solar-S™ Used With Screws: When used with three (3) screws, interbody devices with a lordotic angle ≤ 20° can be used as standalone interbody fusion devices at 1 or 2 contiguous levels. Hyperlordotic interbody devices (>20° lordosis) used with screws, must always be used with supplemental fixation, and may be used at 1 or 2 levels. • Solar-A™: These devices are intended to be used 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™ ALIF Spacers (Without Integrated Fixation) Solar-M™ ALIF 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), spondylolilsthesis, 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 has at least six (6) months of non-operative treatment. Solar-M™ ALIF 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).

510(k) Summary of Safety and Effectiveness

	Hyperlordotic interbody devices (≥20° lordosis) must be used with at least anterior supplemental fixation.
Technological Characteristics	There are no technological differences between the subject and predicate device. 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	Non-clinical testing was performed to demonstrate the DeGen Medical Solar™ Lumbar Interbody Fusion System is substantially equivalent to other predicate devices in accordance with "Guidance for Industry and FDA Staff, Guidance for Spinal System 510(k)s", May 3, 2004 and Class II Special Controls Guidance Document: Intervertebral Body Fusion Device, June 12, 2007. The following tests were performed to show equivalency: • Static and dynamic compression testing per ASTM F2077 • Static and dynamic compression shear testing per ASTM F2077 • Subsidence testing via ASTM F2267 • Expulsion testing • Wear debris characterization per ASTM F1877 The results of these studies show the subject DeGen Medical Solar™ Lumbar Interbody Fusion 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 Solar™ Lumbar Interbody Fusion System is as safe and as effective as the legally marketed predicate.