August 30, 2021

DeGen Medical
% Linda Braddon, Ph.D.
President/CEO
Secure BioMed Evaluations
7828 Hickory Flat Highway Suite 120
Woodstock, Georgia 30188

Re: K210090
Trade/Device Name: Impulse AM™ Interbody Fusion System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: MAX
Dated: July 30, 2021
Received: August 2, 2021

Dear Dr. Braddon:

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 L. 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)*

K210090

Device Name

DeGen Medical Impulse AM™ Interbody Fusion System

Indications for Use *(Describe)*

The DeGen Medical Impulse AM™ implant 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 two contiguous levels from L2-S1. DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. The DeGen Medical Impulse AM™ System 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.

510(k) Summary

K210090

In accordance with 21 CFR 807.87 (h) and 21 CRF 807.92, the 510(k) summary for the DeGen Medical Impulse AM™ System is provided below.

Date	August 27, 2021
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 Linda Braddon, Ph.D. 7828 Hickory Flat Highway Suite 120 Woodstock, GA 30188 770-837-2681 Regulatory@SecureBME.com
Trade Name	Impulse AM™ Interbody Fusion System
Common Name	Intervertebral body fusion device
Code– Classification	MAX 21 CFR 888.3080 : Class II
Primary Predicate	DeGen Impulse™ Spacer K201287
Additional Predicates	Alphatec Spine IdentiTi K183705 Choice Spine TiGer Shark K172816
Device Description	DeGen Medical Impulse AM™ System is a lumbar interbody fusion device for posterior and transforaminal lumbar fusion procedures. The Impulse AM™ system includes various lengths, widths, heights, and endplate shapes (curvatures include neutral, lordotic, and anatomic). The DeGen Medical Impulse AM™ device is comprised of a single component that is additively manufactured. The superior and inferior endplates feature porous surfaces to mitigate subsidence and expulsion. The anatomic, lordotic, and neutral configurations feature a posterior face with a threaded hole and slots to rigidly connect to an instrument for surgical insertion. The hyperlordotic configuration features a posterior face with slots to rigidly connect an instrument for surgical insertion. Superior and inferior faces feature a central aperture to constrain bone graft. DeGen Medical's Impulse AM™ Spacers are additively manufactured from Puri-Ti™ titanium powder having a chemical composition conforming to ASTM B348.

510(k) Summary

K210090

Indications for Use	The DeGen Medical Impulse AM™ implant 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 two contiguous levels from L2-S1. DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. The DeGen Medical Impulse AM™ System 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 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 Impulse AM™ 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: • Static and dynamic compression testing per ASTM F2077 • Static and dynamic compression shear testing per ASTM F2077 • Subsidence testing via ASTM F2267 • Expulsion Testing The results of these studies show the subject DeGen Medical Impulse AM™ System is substantially equivalent to the other predicate devices.
Conclusions	Based on the indications for use, technological characteristics, performance testing, and comparison to predicate devices, the subject DeGen Medical Impulse AM™ System is as safe and as effective as the legally marketed predicates.