October 10, 2025

DeGen Medical
℅ Justin Gracyalny
Senior Manager, Regulatory and Technical Compliance
Secure BioMed Evaluations
7828 Hickory Flat Hwy
Woodstock, Georgia 30188

Re: K252737
Trade/Device Name: DeGen Medical Latitude-C AM™ Cervical Interbody Fusion System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: ODP
Dated: August 28, 2025
Received: August 28, 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,

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

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.	K252737

Please provide the device trade name(s).

DeGen Medical Latitude-C AM™ Cervical Interbody Fusion System

Please provide your Indications for Use below.

The Latitude-C AM™ Interbody Spacer is indicated for spinal fusion procedures at one or more levels in the cervical spine (C2-T1), in skeletally mature patients with degenerative disc disease. Degenerative disc disease is defined as neck pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies.

The Latitude-C AM™ Interbody Spacer is intended for use with autograft and/or allograft comprised of cancellous and/or corticocancellous bone graft and supplemental fixation, eg. Cyclops™ Anterior Cervical Plate System.

Patients must have undergone a regimen of at least six weeks of non-operative treatment prior to being treated with the Latitude-C AM™ Interbody Spacer in the cervical spine.

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 of Safety and Effectiveness

Date	October 7, 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 Spencer Massey 7828 Hickory Flat Highway Woodstock, GA 30188 770-837-2681 Regulatory@SecureBME.com
Trade Name	DeGen Medical Latitude-C AM™ Cervical Interbody Fusion System
Common Name	Intervertebral body fusion device
Code–Classification	ODP 21 CFR 888.3080 : Class II
Primary Predicate	K151496 DeGen Medical Latitude-C Cervical Interbody Spacer System
Additional Predicates	K240326 DeGen Medical Solar™ Lumbar Interbody Fusion System K222270 Globus Medical Hedron C Cervical Spacer K173128 Alliance Partners, LLC Alamo C
Device Description	The DeGen Medical Latitude-C AM™ Cervical Interbody Fusion System is an additively manufactured anterior cervical interbody fusion system for anterior cervical fusion procedures. Latitude-C AM™ cervical spacers are comprised of a single component that is additively manufactured. Latitude-C AM™ spacers are available in the following configurations; lordotic, anatomic, and symmetric. The superior and inferior sides of the endplates of the spacer feature porous surfaces to facilitate fusion and mitigate subsidence and expulsion and feature a central aperture to constrain bone graft. Latitude-C AM™ spacers include various depths, widths, heights, and angles of lordosis. Latitude-C AM™ spacers are additively manufactured from Puri-Ti™ unalloyed titanium.

510(k) Summary of Safety and Effectiveness

Indications for Use	The Latitude-C AM™ Interbody Spacer is indicated for spinal fusion procedures at one or more levels in the cervical spine (C2-T1), in skeletally mature patients with degenerative disc disease. Degenerative disc disease is defined as neck pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies. The Latitude-C AM™ Interbody Spacer is intended for use with autograft and/or allograft comprised of cancellous and/or corticocancellous bone graft and supplemental fixation, eg. Cyclops™ Anterior Cervical Plate System. Patients must have undergone a regimen of at least six weeks of non-operative treatment prior to being treated with the Latitude-C AM™ Interbody Spacer in the cervical spine.
Technological Characteristics	The subject is identical in intended use, indications for use, design, function and technology to the predicate devices. The primary difference between the subject and predicate devices relates to the subject device implants being additively manufactured while the predicate device implants are subtractively manufactured. This difference is addressed via performance testing and identical manufacturing to the predicate (K240326). Any differences in the size offerings were made to include sizes comparable to the cleared predicates (K222270, K173128). 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	Non-clinical testing was performed to demonstrate the DeGen Medical Latitude-C AM™ Cervical Interbody Fusion System is substantially equivalent to predicate device in accordance with Class II Special Controls Guidance Document: Intervertebral Body Fusion Device, June 12, 2007. The following tests were performed to demonstrate equivalency: • Static and dynamic compression testing per ASTM F2077 • Static and dynamic compression shear testing per ASTM F2077 • Static and dynamic torsion testing per ASTM F2077 • Subsidence testing per ASTM F2267 • Expulsion Testing • Mass loss characterization per ASTM F1877 The results of these studies show the subject DeGen Medical Latitude-C AM™ Cervical Interbody Fusion System is substantially equivalent to the predicate device.

510(k) Summary of Safety and Effectiveness

Conclusions	Based on the indications for use, technological characteristics, performance testing, and comparison to the predicate device, the subject DeGen Medical Latitude-C AM™ Cervical Interbody Fusion System is as safe and as effective as the legally marketed predicate device.