May 28, 2026

Global Biomedica s.r.o.
% Robert Poggie
President
BioVera, Inc.
65 Promenade Saint Louis
Notre-Dame-De-L'Ile-Perrot, QC J7W3J6
Canada

Re: K253894
Trade/Device Name: BMD Titanium Spinal Fusion System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: MAX, ODP
Dated: May 4, 2026
Received: May 5, 2026

Dear Dr. Poggie:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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,

KATHERINE D. KAVLOCK -S

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

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K253894

Please provide the device trade name(s).

BMD Titanium Spinal Fusion System

Please provide your Indications for Use below.

BMD Titanium ACIF GW implants are intervertebral body fusion devices intended for use for anterior cervical interbody fusion in skeletally mature patients with cervical disc degeneration and/or cervical spinal instability, as confirmed by imaging studies (radiographs, CT, MRI), that results in radiculopathy, myelopathy, and/or pain at multiple contiguous levels from C2 - T1. The BMD Titanium ACIF GW implants are also to be used with supplemental fixation systems that have been cleared for use in the cervical spine. The BMD Titanium ACIF GW implants are designed for use with autogenous and/or allogeneic bone graft comprised of cancellous, and/or corticocancellous bone graft to facilitate fusion.
BMD Titanium PLIF GW, TLIF GW, ALIF, and LLIF implants in combination with supplemental fixation are indicated for use with autogenous bone graft in patients with degenerative disc disease (DDD) at one or two contiguous spinal levels from L2 – S1 whose condition requires the use of interbody fusion. Degenerative disc disease is defined as discogenic pain with degeneration of the disc confirmed by patient history and radiographic studies. These DDD patients may have up to Grade I spondylolisthesis or retrolisthesis at the involved level(s). These patients may have had a previous non-fusion spinal surgery at the involved spinal level(s). Patients must be skeletally mature. Patients should have received 6 months of nonoperative treatment prior to treatment with the devices.

Please select the types of uses (select one or both, as applicable).

- ☒ Prescription Use (21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

510(k) #: K253894

510(k) Summary

Prepared on: 2026-05-04

Contact Details

21 CFR 807.92(a)(1)

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Correspondent Contact	Dr. Robert Poggie
Correspondent Contact Email	orthobob@biovera.ca

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	BMD Titanium Spinal Fusion System
Common Name	Intervertebral body fusion device
Classification Name	Intervertebral Fusion Device With Bone Graft, Lumbar
Regulation Number	888.3080
Product Code(s)	MAX, ODP INTERVERTEBRAL FUSION DEVICE WITH BONE GRAFT

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K201605	EIT Cellular Titanium ALIF Cage, EIT Cellular Titanium TLIF Cage, EIT Cellular Titanium LLIF Cage, EIT Cellular Titanium T/ PLIF Cage	MAX
K201605	EIT Cellular Titanium Cervical Cage	ODP
K191812	ADI Cervical Interbody Fusion Device	ODP
K193153	SPIRA-C Integrated Fixation System	OVE

Device Description Summary

21 CFR 807.92(a)(4)

The BMD Titanium Spinal Fusion System consists of interbody spinal fusion implants that are designed for use in the cervical and lumbar

spine. BMD Spinal Fusion System implants are intended to be used with bone graft material placed within the void spaces of the implant and with supplemental internal fixation devices that are cleared by the FDA for use in the lumbar spine and cervical spine. BMD Titanium Spinal Fusion System implants are additively manufactured (ADM) by direct metal laser sintering of Ti-6Al-4V alloy ELI powder with chemical composition and mechanical properties conforming to ASTM F136, ASTM F3001, and ASTM F3302. The ADM implants possess a microscopic roughened surface with micro and nano- scale features on the surfaces, including the superior, inferior, and peripheral surfaces of the internal porous structure. These surface characteristics contribute to initial stability and resistance to expulsion. The pore size of the ADM structure is 500 to 700 microns with 70 to 80% porosity.

BMD Titanium ACIF GW implants are designed for anterior cervical fusion and provided in heights 4 to 10mmin 1 mm increments, lengths 12 to 16 mm, and widths 14 to 18 mm, with 0, 5, 10 degrees lordosis options. ACIF GW implants possess topographical features that resist expulsion forces.

BMD Titanium PLIF GW implants are designed for posterior stabilization of the lumbar spine. PLIF GW implants include an integral lumen for graft material and a contoured design to facilitate insertion. PLIF GW implants have heights 9 to12 mm, lengths 20 to 33 mm, and widths 7 to 17 mm in 1 mm increments, with 0, 4, 8, 12, 16, and 20 degrees lordosis options.

BMD Titanium TLIF GW implants are designed for posterior stabilization of the lumbar spine. TLIF GW implants are banana-shaped with a contoured design to facilitate insertion and an integral lumen for graft material. TLIF GW implants range have heights of 7 to 17mm in 1 mm increments, lengths 26 to 34 mm, and widths 10 to 12 mm, with 0, 4, 8, and 12 degrees lordosis options.

BMD Titanium ALIF implants are designed for anterior stabilization of the lumbar spine. ALIF implants are contoured to facilitate insertion. ALIF implants range in heights 9 to 19 mm in 2 mm increments, lengths of 24 to 30 mm, widths 32 to 40 mm, with 5, 10, 15, and 20 degrees of lordosis options.

BMD Titanium LLIF implants are designed for the oblique and lateral approach to the lumbar spine. LLIF implants have a contoured forward edge to facilitate insertion. LLIF implants range in LLIF implants range in heights 7 to 17 mm in 2 mm increments, lengths of 40 to 60 mm, and widths of 18 to 22 mm, with 0, 6 and 12 degrees lordosis options.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

BMD Titanium ACIF GW implants are intervertebral body fusion devices intended for use for anterior cervical interbody fusion in skeletally mature patients with cervical disc degeneration and/or cervical spinal instability, as confirmed by imaging studies (radiographs, CT, MRI), that results in radiculopathy, myelopathy, and/or pain at multiple contiguous levels from C2 - T1. The BMD Titanium ACIF GW implants are also to be used with supplemental fixation systems that have been cleared for use in the cervical spine. The BMD Titanium ACIF GW implants are designed for use with autogenous and/or allogeneic bone graft comprised of cancellous, and/or corticocancellous bone graft to facilitate fusion.

BMD Titanium PLIF GW, TLIF GW, ALIF, and LLIF implants in combination with supplemental fixation are indicated for use with autogenous bone graft in patients with degenerative disc disease (DDD) at one or two contiguous spinal levels from L2 – S1 whose condition requires the use of interbody fusion. Degenerative disc disease is defined as discogenic pain with degeneration of the disc confirmed by patient history and radiographic studies. These DDD patients may have up to Grade I spondylolisthesis or retrolisthesis at the involved level(s). These patients may have had a previous non-fusion spinal surgery at the involved spinal level(s). Patients must be skeletally mature. Patients should have received 6 months of nonoperative treatment prior to treatment with the devices.

Indications for Use Comparison

21 CFR 807.92(a)(5)

The BMD Titanium Spinal Fusion System has the same indications for use as the primary predicate device, EIT Cellular Titanium Cervical and Lumbar Cages (K201605).

Technological Comparison

21 CFR 807.92(a)(6)

The BMD Titanium Spinal Fusion System has the same technological characteristics as the predicate devices, EIT Cellular Titanium Cervical and Lumbar Cages (K201605). Both the subject and predicate devices are produced using additive manufacturing and have similar design in terms of shape, height, depth/length, angle, porosity, and amount and location of void-space / lumens integral to the implant for containment of bone graft material. The predicate and subject devices both provide graft-windows (e.g. lumens; hollow geometry within the implant) that can be packed with bone graft material. The subject and predicate devices are made of the same material, namely medical additively manufactured (ADM) Ti6Al4V ELI alloy per ASTM F3001. Also similar to the predicate device, the subject BMD Titanium Spinal Fusion Implants possess a microscopic roughened surface with micro and nano-scale features that are an inherent artifact of the ADM process. The micro and nano features are found on all surfaces of the subject device implants, including the superior, inferior, and peripheral surfaces, as well as each member of the internal structure that comprises the implants. The BMD Titanium Implants (cervical: ACIF GW and lumbar: TLIF GW, PLIF GW, ALIF, LLIF) are substantially equivalent to the primary predicate EIT device with respect to indications for use and technological characteristics (design, size range, function, materials, performance, intended use).

Non-Clinical and/or Clinical Tests Summary & Conclusions

21 CFR 807.92(b)

Mechanical testing of the subject cervical spinal cage fusion device was conducted by CENIC Test Laboratory which is accredited to ISO/IEC 17025 and ilac-MRA requirements. Mechanical testing was performed on worst case cervical and lumbar (PLIF) devices. To identify

worst case devices for mechanical testing, engineering analyses were performed on the cervical and lumbar devices. The tests performed on the worst-case cervical and PLIF devices were:

- Static Compression ASTM F2077-22
- Fatigue Compression ASTM F2077-22
- Static Shear ASTM F2077-22
- Fatigue Shear ASTM F2077-22
- Static Torsion ASTM F2077-22
- Fatigue Torsion ASTM F2077-22
- Subsidence ASTM F2267-24
- Expulsion Industry standardized test method

Performance characteristics of the devices were assessed per the FDA Guidance Document entitled "Class II Special Controls Guidance Document: Intervertebral Body Fusion Device" issued on June 12, 2007. The acceptance criteria for the cervical implants were derived from reference 1: "Jonathan H Peck, David C Sing, Srinidhi Nagaraja, Deepa G Peck, Jeffrey C Lotz, Anton E Dmitriev, Mechanical performance of cervical intervertebral body fusion devices: A systematic analysis of data submitted to the Food and Drug Administration, J Biomech. 2017 Mar 21;54:26-32. doi: 10.1016/j.jbiomech.2017.01.032. The acceptance criteria for the lumbar implants were derived from reference 2: "Jonathan H. Peck, Katherine D. Kavlock, Brent L. Showalter, Brittany M. Ferrell, Deepa G. Peck, Anton E. Dmitriev, Mechanical performance of lumbar intervertebral body fusion devices: An analysis of data submitted to the Food and Drug Administration, Journal of Biomechanics 78 (2018) 87–93".

The additive manufacturing (ADM) process for the subject devices was validated for chemistry, strength, dimensions of devices, cleanliness, and powder reuse. ADM Manufacturing Process validation was performed for Global Biomedica's two EOS ADM Machines. The work was divided into installation, operational, and production qualifications (IQ, OQ, PQ). The powder reuse was validated per industry standards, including ASTM F3001, ISO 13320 / ASTM B822 / ASTM B214, ASTM B212, ISO 3369, ISO/ASTM 52928:2024, MDR (EU 2017/745), FDA (21 CFR 820), Health Canada (SOR/98-282), ANVISA RDC 665/2022, and ISO 13485. Cleaning and passivation of subject implant devices is compliant with ASTM F86-21. Cleanliness and particulate analysis was conducted in accordance with ASTM F1877 and regulatory expectations for metallic implantable medical devices under FDA, Health Canada, ANVISA, and MDR (EU) jurisdictions.

MRI characteristics of the subject device were tested to establish labeling for MRI Safety.

Subject devices were tested for endotoxins using the LAL test per ISO 11737-3 as amended and ANSI_AAMI ST72:2019 Bacterial Endotoxins. Acceptance criterion was met (< of 20 EUs).

The subject device was demonstrated to be substantially equivalent to predicate device with respect to indications for use, design, materials, function, manufacturing, and performance testing relative to the acceptance criteria per FDA guidance documents and ASTM standards F2077 and F2267. Bacterial endotoxin testing was performed as part of the sterilization validation and met acceptance criteria. The subject BMD Titanium Spinal Fusion Implants are substantially equivalent to previously cleared devices with respect to its indications for use, design, function, materials, and performance.