December 22, 2025

Globus Medical, Inc.
Dr. Jennifer Antonacci
Director, Regulatory Affairs
Valley Forge Business Center
2560 General Armistead Ave.
Audubon, Pennsylvania 19403

Re: K253876
Trade/Device Name: HEDRON™ Cervical Spacers (HEDRON C-MIS™ Spacer)
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: OVE, ODP
Dated: December 3, 2025
Received: December 4, 2025

Dear Dr. Antonacci:

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,

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.	K253876

Please provide the device trade name(s).

HEDRON™ Cervical Spacers (HEDRON C-MIS™ Spacer)

Please provide your Indications for Use below.

HEDRON C™ Spacers and HEDRON IC™ Spacers are interbody fusion devices indicated at one or more levels of the cervical spine (C2-T1) in patients with cervical disc disease, instability, trauma including fractures, deformity defined as kyphosis, lordosis, or scoliosis, cervical spondylotic myelopathy, spinal stenosis, and failed previous fusion. Cervical disc disease is defined as intractable radiculopathy and/or myelopathy with herniated disc and/or osteophyte formation on posterior vertebral endplates producing symptomatic nerve root and/or spinal cord compression confirmed by radiographic studies. These patients should be skeletally mature and have had at least six (6) weeks of non-operative treatment.

HEDRON C™ Spacers and HEDRON IC™ Spacers are intended to be used with supplemental fixation, such as an anterior cervical plate or posterior cervical fixation.

When the HEDRON IC™ Spacer is used with the COALITION AGX™ Plate, the plate-spacer assembly (HEDRON IC™ Plate-Spacer) is a stand-alone device intended for use at one or two levels of the cervical spine (C2-T1) in patients with cervical disc disease, instability, trauma including fractures, deformity defined as kyphosis, lordosis, or scoliosis, cervical spondylotic myelopathy, spinal stenosis, and failed previous fusion. These devices are to be used with two titanium alloy screws which accompany the implant. Hyperlordotic implants (≥20°) must be used with supplemental fixation in addition to the two screws.

HEDRON C-MIS™ Spacer is an integrated interbody fusion device indicated for use at one or two levels of the cervical spine (C2-T1) in patients with cervical disc disease, instability, trauma including fractures, deformity defined as kyphosis, lordosis, or scoliosis, cervical spondylotic myelopathy, spinal stenosis, and failed previous fusion. These devices are intended to be used with or without two screws and/or anchors which accompany the implants. When used with two screws, these devices are intended for stand-alone use at one or two levels. When used with one or more anchors, these devices are intended for use at one level of the cervical spine (C2-T1) with additional supplemental fixation, such as an anterior cervical plate or posterior cervical screw fixation. Hyperlordotic implants (≥20°) must be used with supplemental fixation in addition to the two screws or anchors.

HEDRON™ Cervical Spacers are to be filled with autograft bone and/or allogenic bone graft composed of cancellous, cortical, and/or corticocancellous bone or a bone void filler as cleared by the FDA for use in intervertebral body fusion to facilitate fusion.

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) Summary: HEDRON™ Cervical Spacers

Company: Globus Medical Inc.
2560 General Armistead Ave.
Audubon, PA 19403
610-930-1800

Primary Contact: Jennifer Antonacci, Ph.D.
Director, Regulatory Affairs

Secondary Contact: Katherine Warren
Regulatory Specialist

Date Prepared: December 17, 2025

Device Name: HEDRON™ Cervical Spacers (HEDRON C-MIS™ Spacer)

Common Name: Intervertebral Body Fusion Device

Classification: Per 21 CFR as follows:
§888.3080 Intervertebral Body Fusion Device
Product Code(s): ODP, OVE
Regulatory Class II, Panel Code: 87

Primary Predicate: HEDRON™ Cervical Spacers (K222270)

Additional Predicates: HEDRON™ Cervical Spacers (K191243)
COALITION MIS™ Spacer (K151939, K173115)
CoRoent Small Interlock II (K231735)

Purpose:
The purpose of this submission is to request clearance for the HEDRON C-MIS™ Spacer as a line extension to HEDRON™ Cervical Spacers. Additional indications for cleared HEDRON™ Cervical Spacers are also being requested.

Device Description:
HEDRON™ Cervical Spacers (HEDRON C™, HEDRON IC™, and HEDRON C-MIS™) are anterior cervical interbody fusion devices used to provide structural stability in skeletally mature individuals following discectomy. HEDRON IC™ Spacer may be assembled to the COALITION AGX™ Plate to create the HEDRON IC™ Plate-Spacer, a stand-alone cervical interbody fusion device. HEDRON C-MIS™ Spacer is a cervical interbody fusion device that may be used with screws and/or anchors. HEDRON C-MIS™ is a stand-alone device when used with screws only. HEDRON™ Cervical Spacers are additively manufactured from titanium alloy powder. The mating screws and anchors are manufactured from titanium alloy.

Indications for Use:
HEDRON C™ Spacers and HEDRON IC™ Spacers are interbody fusion devices indicated at one or more levels of the cervical spine (C2-T1) in patients with cervical disc disease, instability, trauma including fractures, deformity defined as kyphosis, lordosis, or scoliosis, cervical spondylotic myelopathy, spinal stenosis, and failed previous fusion. Cervical disc disease is defined as intractable radiculopathy and/or myelopathy with herniated disc and/or osteophyte formation on posterior vertebral endplates producing symptomatic nerve root and/or spinal cord compression confirmed by radiographic studies. These patients should be skeletally mature and have had at least six (6) weeks of non-operative treatment.

HEDRON C™ Spacers and HEDRON IC™ Spacers are intended to be used with supplemental fixation, such as an anterior cervical plate or posterior cervical fixation.

When the HEDRON IC™ Spacer is used with the COALITION AGX™ Plate, the plate-spacer assembly (HEDRON IC™ Plate-Spacer) is a stand-alone device intended for use at one or two levels of the cervical spine (C2-T1) in patients with cervical disc disease, instability, trauma including fractures, deformity defined as kyphosis, lordosis, or scoliosis, cervical spondylotic myelopathy, spinal stenosis, and failed previous fusion. These devices are to be used with two titanium alloy screws which accompany the implant. Hyperlordotic implants (≥20°) must be used with supplemental fixation in addition to the two screws.

HEDRON C-MIS™ Spacer is an integrated interbody fusion device indicated for use at one or two levels of the cervical spine (C2-T1) in patients with cervical disc disease, instability, trauma including fractures, deformity defined as kyphosis, lordosis, or scoliosis, cervical spondylotic myelopathy, spinal stenosis, and failed previous fusion. These devices are intended to be used with or without two screws and/or anchors which accompany the implants. When used with two screws, these devices are intended for stand-alone use at one or two levels. When used with one or more anchors, these devices are intended for use at one level of the cervical spine (C2-T1) with additional supplemental fixation, such as an anterior cervical plate or posterior cervical screw fixation. Hyperlordotic implants (≥20°) must be used with supplemental fixation in addition to the two screws or anchors.

HEDRON™ Cervical Spacers are to be filled with autograft bone and/or allogenic bone graft composed of cancellous, cortical, and/or corticocancellous bone or a bone void filler as cleared by the FDA for use in intervertebral body fusion to facilitate fusion.

Performance Data:
Mechanical testing (static and dynamic compression, torsion and compression-shear, subsidence, and expulsion) was conducted in accordance with the "Guidance for Industry and FDA Staff, Class II Special Controls Guidance Document: Intervertebral Fusion Device," June 12, 2007, ASTM F2077, and ASTM F2267. Performance data demonstrate substantial equivalence to the predicate devices.

Technological Characteristics:
The HEDRON™ Cervical Spacers have similar technological characteristics as the predicate devices including overall design, intended use, material composition, function, and range of sizes.

Basis of Substantial Equivalence:
The HEDRON™ Cervical Spacers have been found to be substantially equivalent to the predicate devices with respect to technological characteristics, performance, design, and intended use. The information provided within this premarket notification supports substantial equivalence to the predicate devices.