April 29, 2026

Globus Medical, Inc.
Jennifer Antonacci, Ph.D.
Director, Regulatory Affairs
2560 General Armistead Ave.
Audubon, Pennsylvania 19403

Re: K253401
Trade/Device Name: SCRIPT™ Implant System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: OVD, MAX, PHM, OLO, SBF
Dated: March 18, 2026
Received: March 19, 2026

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 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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K253401

Device Name
SCRIPT™ Implant System

Indications for Use *(Describe)*
SCRIPT™ Lumbar Spacers, including SCRIPT ALIF™, SCRIPT XLIF™, SCRIPT XLIF EX™, SCRIPT TLIF™, SCRIPT TLIF EX™, and SCRIPT TLIF-A™, 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), spondylolisthesis, deformity (degenerative scoliosis or kyphosis), spinal stenosis, and failed previous fusion (pseudarthrosis). DDD is defined as discogenic back pain with degeneration of the disc as confirmed by history and radiographic studies. These patients should be skeletally mature and have had at least six (6) months of non-operative treatment. SCRIPT™ Lumbar Spacers are to be filled with autograft bone and/or allogenic bone graft composed of cancellous and/or corticocancellous bone or a bone void filler as cleared by the FDA for use in intervertebral body fusion to facilitate fusion. 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, and anterior screw and rod systems). Hyperlordotic interbody devices (≥20° lordosis) must be used with at least anterior supplemental fixation.

SCRIPT ALIF IA™ Lumbar Spacers are integrated lumbar interbody fusion devices indicated for use at one or more levels of the 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), spondylolisthesis, 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 had at least six (6) months of non-operative treatment. These devices are intended to be used with or without three screws and/or anchors which accompany the implants. These devices are intended for use with supplemental fixation (e.g. facet screws or posterior fixation). In addition, these devices are intended for stand-alone use in patients with DDD at one or two levels only when ≤20° lordotic implants are used with three screws per implant. SCRIPT™ ALIF IA Lumbar Spacers are to be filled with autograft bone and/or allogenic bone graft composed of cancellous and/or corticocancellous bone or a bone void filler as cleared by the FDA for use in intervertebral body fusion to facilitate fusion.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary: SCRIPT™ Implant System

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

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

Secondary Contact: Katherine Warren
Regulatory Specialist

Date Prepared: April 28, 2026

Device Name: SCRIPT™ Implant System

Common Name: Intervertebral Body Fusion Device
Stereotaxic Instruments

Classification: <u>SCRIPT™ Lumbar Spacers</u>
Per 21 CFR as follows:
§888.3080 Intervertebral Body Fusion Device
Product Code(s): MAX, OVD, PHM
Regulatory Class: II, Panel Code: 87

<u>ExcelsiusGPS® Instruments</u>
Per 21 CFR as follows:
§882.4560 Stereotaxic Instruments
Product Codes OLO, SBF
Regulatory Class: II, Panel Code: 87

Primary Predicate: HEDRON™ Lumbar Spacers & SABLE™ Expandable Spacer (K222270)

Other Predicates: RISE™ Spacers (K221894)
Carlsmed aprevo lumbar interbody fusion devices (K222082, K243635)
Modulus™ Interbody Systems (K203714)
MOD-EX XLIF™ Interbody System (K220478)

Reference Devices: ExcelsiusGPS™ (K191100)
ExcelsiusHub™ (K211616)
ExcelsiusXR™ (K241525)

Purpose:
The purpose of this submission is to request clearance for the SCRIPT™ Implant System, including patient-specific lumbar interbody fusion devices (Lumbar Spacers). SCRIPT™ Lumbar Spacers may also be used with compatible ExcelsiusGPS™ instruments for use with ExcelsiusGPS™, ExcelsiusHub™, and/or ExcelsiusXR™.

Device Description:

SCRIPT™ Lumbar Spacers
SCRIPT™ Lumbar Spacers are lumbar interbody fusion devices used to provide structural stability following discectomy. Each SCRIPT™ spacer is designed with patient-matched endplates to accommodate the topography of the patient's vertebral endplates. SCRIPT™ Spacers include static, static integrated (designated by IA), and expandable (designated by EX) designs, and are offered in different shapes and footprints to accommodate various surgical approaches to the spine, including anterior, anterolateral, lateral, posterior, or transforaminal approaches. SCRIPT™ integrated spacers are anterior lumbar interbody fusion devices used with or without screws and/or anchors.

All SCRIPT™ Lumbar Spacers are manufactured from titanium alloy. The static SCRIPT™ spacers and the endplates of the expandable SCRIPT™ spacers are additively manufactured from titanium powder. The internal components of the expandable SCRIPT™ spacers are manufactured from wrought titanium alloy and radiolucent PEEK polymer, and the drive screw is manufactured from wrought cobalt chromium or titanium alloy.

ExcelsiusGPS™ Instruments
ExcelsiusGPS™ Instruments are nonsterile, reusable instruments that can be used with ExcelsiusGPS™, ExcelsiusHub™ and ExcelsiusXR™ for navigated surgical placement of interbody fusion devices.

Indications for Use:

SCRIPT™ Lumbar Spacers
SCRIPT™ Lumbar Spacers, including SCRIPT ALIF™, SCRIPT XLIF™, SCRIPT XLIF EX™, SCRIPT TLIF™, SCRIPT TLIF EX™, and SCRIPT TLIF-A™, 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), spondylolisthesis, deformity (degenerative scoliosis or kyphosis), spinal stenosis, and failed previous fusion (pseudarthrosis). DDD is defined as discogenic back pain with degeneration of the disc as confirmed by history and radiographic studies. These patients should be skeletally mature and have had at least six (6) months of non-operative treatment. SCRIPT™ Lumbar Spacers are to be filled

with autograft bone and/or allogenic bone graft composed of cancellous and/or corticocancellous bone or a bone void filler as cleared by the FDA for use in intervertebral body fusion to facilitate fusion. 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, and anterior screw and rod systems). Hyperlordotic interbody devices (≥20° lordosis) must be used with at least anterior supplemental fixation.

SCRIPT ALIF IA™ Spacers are integrated lumbar interbody fusion devices indicated for use at one or more levels of the 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), spondylolisthesis, 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 had at least six (6) months of non-operative treatment. These devices are intended to be used with or without three screws and/or anchors which accompany the implants. These devices are intended for use with supplemental fixation (e.g. facet screws or posterior fixation). In addition, these devices are intended for stand-alone use in patients with DDD at one or two levels only when ≤20° lordotic implants are used with three screws per implant. SCRIPT™ ALIF IA Spacers are to be filled with autograft bone and/or allogenic bone graft composed of cancellous and/or corticocancellous bone or a bone void filler as cleared by the FDA for use in intervertebral body fusion to facilitate fusion.

Performance Testing:
Mechanical testing (axial compression, 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 to demonstrate substantial equivalence to the predicate devices.

Verification and validation testing were conducted to confirm that the SCRIPT™ implants meet performance requirements. The following testing was conducted:

- Cadaveric Usability testing under clinically relevant scenarios. This testing demonstrated that:
    - SCRIPT™ Lumbar Spacers as planned and manufactured met the requirements of contouring to the endplates, and were designed per the plan
- Non-clinical system, software, and instrument verification and validation - demonstrated compliance with user needs and corresponding design inputs
- Instrument integration testing verified system accuracy was maintained for navigating SCRIPT™ Lumbar Spacers with ExcelsiusGPS™ Instruments

Technological Characteristics:
Subject implants have the same or similar technological characteristics as the predicate devices including design, intended use, material composition, function, and range of sizes.

Basis of Substantial Equivalence:
Subject devices have been found to be substantially equivalent to the predicate devices with respect to technical characteristics, performance, and intended use. The information provided within this premarket notification supports substantial equivalence of the subject devices to the predicate devices.