October 21, 2022

Globus Medical Inc.
Kelly Baker, Ph.D.
Senior Vice President, Regulatory and Clinical Affairs
2560 General Armistead Ave.
Audubon, Pennsylvania 19403

Re: K222270
Trade/Device Name: HEDRON® Cervical Spacers, HEDRON® Lumbar Spacers, SABLE® Expandable Spacer, ExcelsiusGPS® Instruments
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: ODP, OVE, OVD, PHM, MAX, OLO
Dated: July 28, 2022
Received: July 29, 2022

Dear Kelly Baker:

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 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)*
K222270

Device Name
HEDRON® Cervical Spacers

Indications for Use *(Describe)*

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. These devices are to be filled with autograft bone and/or allogenic bone graft composed of cancellous, cortical, and/or corticocancellous bone.

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.

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.

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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)*
K222270

Device Name
HEDRON® Lumbar Spacers

Indications for Use *(Describe)*
HEDRON® Lumbar Spacers (HEDRON A™, HEDRON L®, HEDRON P®, HEDRON T™, and HEDRON RT™) 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. HEDRON® Spacers are to be filled with autograft bone and/or allogenic bone graft composed of cancellous and/or corticocancellous bone. 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.

HEDRON IA® Integrated 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 <25° lordotic implants are used with three screws per implant. HEDRON IA® Spacers are to be filled with autograft bone and/or allogenic bone graft composed of cancellous and/or corticocancellous bone.

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)

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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)*

K222270

Device Name
SABLE® Expandable Spacer

Indications for Use *(Describe)*

SABLE® Expandable Spacer is an interbody fusion device intended for use 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 confirmed by history and radiographic studies. These patients should be skeletally mature and have had at least six (6) months of non-operative treatment. The spacer is to be filled with autograft and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone and is 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).

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)

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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)*
K222270

Device Name
ExcelsiusGPS®

Indications for Use *(Describe)*
The ExcelsiusGPS® is intended for use as an aid for precisely locating anatomical structures and for spatial positioning and orientation of an instrument holder or guide tube to be used by surgeons for navigating and/or guiding compatible surgical instruments in open or percutaneous procedures provided that the required fiducial markers and rigid patient anatomy can be identified on CT scans or fluoroscopy. The system is indicated for the placement of spinal and orthopedic bone screws and interbody spacers.

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)

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510(k) Summary: HEDRON® Cervical & Lumbar Spacers, SABLE® Expandable Spacer

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

Contact: Kelly Baker, Ph.D.
Senior Vice President, Regulatory and Clinical Affairs

Date Prepared: October 14, 2022

Device Name: HEDRON® Cervical Spacers
HEDRON® Lumbar Spacers
SABLE® Expandable Spacer
ExcelsiusGPS® Instruments

Common Name: Intervertebral Body Fusion Device
Stereotaxic Instruments

Classification:

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

HEDRON® Lumbar Spacers
Per 21 CFR as follows:
§888.3080 Intervertebral Body Fusion Device
Product Code(s): OVD, PHM, MAX
Regulatory Class: II, Panel Code: 87

SABLE® Expandable Spacer
Per 21 CFR as follows:
§888.3080 Intervertebral Body Fusion Device
Product Code(s): MAX
Regulatory Class: II, Panel Code: 87

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

Primary Predicate: HEDRON® Cervical Spacers (K191243)

Additional Predicates:
HEDRON® Lumbar Spacers (K191391, K203278)
SABLE® Expandable Spacer (K192115)
ExcelsiusGPS® (K191100)

Purpose:
The purpose of this submission is to request clearance for updates to HEDRON® Cervical Spacers, HEDRON® Lumbar Spacers, SABLE® Expandable Spacer, and associated ExcelsiusGPS® instruments.

Device Description:
HEDRON® Cervical Spacers
HEDRON® Cervical Spacers (HEDRON C® and HEDRON IC®) 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® Spacers are additively manufactured from titanium alloy, as specified in ASTM F3001.

HEDRON® Lumbar Spacers
HEDRON® Lumbar Spacers are lumbar interbody fusion devices used to provide structural stability following discectomy. Each HEDRON® spacer has a different shape to accommodate various surgical approaches to the spine, including anterior, anterolateral, lateral, posterior or transforaminal approaches. All approaches are used in the lumbar spine; only anterior, anterolateral, or lateral approaches are used in the thoracic spine.

HEDRON® Integrated Lumbar Spacers are integrated anterior lumbar interbody fusion devices used to provide structural stability following discectomy. They are used with or without screws and/or anchors.

All HEDRON® Lumbar Spacers are additively manufactured from titanium powder. The mating screws and anchors are manufactured from titanium alloy and/or cobalt chrome alloy. Titanium screws and anchors are available with or without hydroxyapatite (HA) coating.

SABLE® Expandable Spacer
The SABLE® Expandable Spacer is an expandable lumbar interbody fusion device used to provide structural stability in skeletally mature individuals following discectomy. The device is available in various heights and geometric options to fit the anatomical needs of a wide variety of patients.

SABLE® Spacers are manufactured from titanium alloy. The endplates are additively manufactured from titanium alloy powder and an internal component is manufactured from radiolucent PEEK polymer. The drive screw is manufactured from cobalt chromium alloy.

ExcelsiusGPS®
ExcelsiusGPS® Instruments are nonsterile, reusable instruments that can be operated with ExcelsiusGPS® and may be used for a freehand navigated surgical procedure.

Indications for Use:
HEDRON® Cervical Spacers
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. These devices are to be filled with autograft bone and/or allogenic bone graft composed of cancellous, cortical, and/or corticocancellous bone.

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® Lumbar Spacers
HEDRON® Lumbar Spacers (HEDRON A™, HEDRON L®, HEDRON P®, HEDRON T™, and HEDRON RT™) 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. HEDRON® Spacers are to be filled with autograft bone and/or allogenic bone graft composed of cancellous and/or corticocancellous bone. 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.

HEDRON IA® Integrated 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 <25° lordotic implants are used with three screws per implant. HEDRON IA® Spacers are to be filled with autograft bone and/or allogenic bone graft composed of cancellous and/or corticocancellous bone.

SABLE® Expandable Spacer

SABLE® Expandable Spacer is an interbody fusion device intended for use 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 confirmed by history and radiographic studies. These patients should be skeletally mature and have had at least six (6) months of non-operative treatment. The spacer is to be filled with autograft and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone and is 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).

ExcelsiusGPS®
The ExcelsiusGPS® is intended for use as an aid for precisely locating anatomical structures and for spatial positioning and orientation of an instrument holder or guide tube to be used by surgeons for navigating and/or guiding compatible surgical instruments in open or percutaneous procedures provided that the required fiducial markers and rigid patient anatomy can be identified on CT scans or fluoroscopy. The system is indicated for the placement of spinal and orthopedic bone screws and interbody spacers.

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

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

Basis of Substantial Equivalence:
Subject HEDRON and SABLE spacers 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 spacers to the predicate devices