February 2, 2021

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

Re: K203278
Trade/Device Name: INDEPENDENCE® Spacers, HEDRON IA™, MAGNIFY-S® Spacers, MONUMENT® Spacers, InterContinental® Plate-Spacer, ELSA® Spacers
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: MAX, OVD
Dated: November 4, 2020
Received: November 6, 2020

Dear Dr. 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K203278

Device Name
INDEPENDENCE® Spacers

Indications for Use *(Describe)*

INDEPENDENCE® Spacers (including INDEPENDENCE MIS® and INDEPENDENCE MIS AGX™) are integrated anterior 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. All INDEPENDENCE® TPS coated spacers are indicated for the same use as non-coated PEEK versions.

INDEPENDENCE® Spacers are intended to be used with or without three screws which accompany the implants. INDEPENDENCE MIS® and INDEPENDENCE MIS AGX™ Integrated Spacers 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.

INDEPENDENCE MIS AGX™ Spacers are C-shaped, non-integrated PEEK spacers that are intended to be used with supplemental fixation (e.g. facet screws or posterior fixation). When used in conjunction with the INDEPENDENCE MIS AGX™ Integrated Ti Spacer, these devices become the INDEPENDENCE MIS AGX™ Integrated Spacer.

All INDEPENDENCE® 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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

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Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K203278

Device Name
HEDRON IA™

Indications for Use *(Describe)*

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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510(k) Number *(if known)*

K203278

Device Name
MAGNIFY®-S Spacers

Indications for Use *(Describe)*

The MAGNIFY®-S Spacer is an interbody fusion device 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.

The MAGNIFY®-S Spacer is to be used with or without three screws which accompany the implant. 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 used with three screws per implant. The MAGNIFY®-S Spacer is 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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See PRA Statement below.

510(k) Number *(if known)*

K203278

Device Name
MONUMENT® Spacers

Indications for Use *(Describe)*

The MONUMENT® Spacer is an interbody fusion device 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), deformity (degenerative scoliosis or kyphosis), spinal stenosis, and failed previous fusion (pseudarthrosis). In addition, these patients may have up to Grade 1 spondylolisthesis or retrolisthesis at the involved level(s). 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 MONUMENT® Spacer is to be used with four screws that accompany the implant. These devices are intended for use with supplemental fixation (e.g. facet screws or posterior fixation). The MONUMENT® Spacer is 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K203278

Device Name
InterContinental® Plate-Spacer

Indications for Use *(Describe)*

InterContinental® Plate-Spacers are lateral 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. All InterContinental® TPS coated spacers are indicated for the same use as non-coated PEEK versions.

InterContinental® Plate-Spacers are intended to be used with or without two screws and/or anchors which accompany the implants. These devices are intended for use with supplemental fixation (e.g. facet screws or posterior fixation). InterContinental® Plate-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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K203278

Device Name
ELSA® Spacers

Indications for Use *(Describe)*

The ELSA® Spacer is an interbody fusion device 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.

The ELSA® Spacer is intended to be used with or without two screws and/or anchors which accompany the implants. These devices are intended for use with supplemental fixation. Hyperlordotic (≥20°) implants must be used with the two screws and/or anchors and supplemental fixation in addition to the two screws and/or anchors. The ELSA® Spacer is to be filled with autograft and/or allogenic bone graft comprised 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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

510(k) Summary: INDEPENDENCE®, HEDRON IA™, MAGNIFY-S®, MONUMENT®, InterContinental®, and ELSA® Additional Implants and Updated Indications

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: January 6, 2021

Device Name: INDEPENDENCE® Spacers
HEDRON IA™
MAGNIFY®-S Spacers
MONUMENT® Spacers
InterContinental® Plate-Spacer
ELSA® Spacers

Common Name: Intervertebral Body Fusion Device

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

Primary Predicate: CORBEL™ Spacers (K201087)

Other Predicates: INDEPENDENCE® Spacers (K082252, K120101, K171848)
INDEPENDENCE MIS® Spacers (K160597)
INDEPENDENCE MIS AGX™ Spacers (K170157)
HEDRON™ Lumbar Spacers (K191391)
MAGNIFY®-S Spacers (K142498)
MONUMENT® Spacers (K132559)
InterContinental® Plate-Spacer (K103382, K161223, K171848)
ELSA® Spacers (K161379)
LDR Avenue-L Lateral Lumbar Cage (K153495)
NuVasive Brigade Lateral System (K181386)
NuVasive CoRoent XL (K201820)

Purpose:
The purpose of this submission is to request clearance for new lateral anchors and cleared locking screws for use with ELSA® and InterContinental® spacers, and to update indications for INDEPENDENCE®, INDEPENDENCE MIS®, INDEPENDENCE MIS AGX®, HEDRON™ IA, MAGNIFY®-S, MONUMENT®, InterContinental®, and ELSA® spacers. Clearance is also requested for additional sterile implants and titanium plasma spray (TPS) coated spacers, and for MR Conditional labeling for the additional implants.

Device Description:
INDEPENDENCE® Spacers
INDEPENDENCE® (including INDEPENDENCE MIS® and INDEPENDENCE MIS AGX™) Spacers are integrated anterior lumbar interbody fusion devices used to provide structural stability in skeletally mature individuals following discectomy. The spacers are available in various heights and geometric options to fit the anatomical needs of a wide variety of patients. Protrusions on the superior and inferior surfaces of each device grip the endplates of the adjacent vertebrae to aid in expulsion resistance. These devices may be used with screws and/or anchors.

HEDRON IA™
HEDRON IA™ Integrated Lumbar Spacers are integrated anterior lumbar interbody fusion devices used to provide structural stability in skeletally mature individuals following discectomy. These devices may be used with screws and/or anchors.

MAGNIFY®-S Spacers
MAGNIFY® Spacers are expandable anterior lumbar interbody fusion devices used to provide structural stability in skeletally mature individuals following discectomy. The devices are available in various height expansion ranges and geometric options to fit the anatomical needs of a wide variety of patients. Protrusions on the superior and inferior surfaces of each device grip the endplates of the adjacent vertebrae to aid in expulsion resistance. The MAGNIFY®-S Spacers are used with screws.

MONUMENT® Spacers
The MONUMENT® Spacer is an anterior lumbar interbody fusion device used to provide structural stability in skeletally mature individuals following discectomy. The MONUMENT® Spacer is intended to aid in reduction of a Grade 1 spondylolisthesis. The spacers are available in various heights and geometric options to fit the anatomical needs of a wide variety of patients. Protrusions on the superior and inferior surfaces of each device grip the endplates of the adjacent vertebrae to aid in expulsion resistance. Screws are inserted through the anterior titanium portion of the implant into adjacent vertebral bodies for bony fixation.

InterContinental® Plate-Spacer
InterContinental® Plate-Spacers are lateral lumbar interbody fusion devices used to provide structural stability in skeletally mature individuals following discectomy. InterContinental® Plate-Spacers are available in various heights and geometric options to fit the anatomical needs of a wide variety of patients. Protrusions on the superior and inferior surfaces grip the endplates of the adjacent vertebrae to aid in expulsion resistance. Bone screws and/or anchors may be used to attach to the lateral portion of the adjacent vertebral bodies for bony fixation.

ELSA® Spacers
ELSA® Spacers are expandable lateral lumbar interbody fusion devices used to provide structural stability in skeletally mature individuals following discectomy. The devices are available in various heights and geometric options to fit the anatomical needs of a wide variety of patients. Protrusions on the superior and inferior surfaces of each device grip the endplates of the adjacent vertebrae to aid in expulsion resistance. Bone screws and/or anchors may be used to attach to the lateral portion of the adjacent vertebral bodies for bony fixation.

Indications for Use:
INDEPENDENCE® Spacers
INDEPENDENCE® Spacers (including INDEPENDENCE MIS® and INDEPENDENCE MIS AGX™) are integrated anterior 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. All INDEPENDENCE® TPS coated spacers are indicated for the same use as non-coated PEEK versions.

INDEPENDENCE® Spacers are intended to be used with or without three screws which accompany the implants. INDEPENDENCE MIS® and INDEPENDENCE MIS AGX™ Integrated Spacers 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.

INDEPENDENCE MIS AGX™ Spacers are C-shaped, non-integrated PEEK spacers that are intended to be used with supplemental fixation (e.g. facet screws or posterior fixation). When used in conjunction with the INDEPENDENCE MIS AGX™ Integrated Ti Spacer, these devices become the INDEPENDENCE MIS AGX™ Integrated Spacer.

All INDEPENDENCE® Spacers are to be filled with autograft bone and/or allogenic bone graft composed of cancellous and/or corticocancellous bone.

HEDRON IA™
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.

MAGNIFY®-S Spacers
The MAGNIFY®-S Spacer is an interbody fusion device 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.

The MAGNIFY®-S Spacer is to be used with or without three screws which accompany the implant. 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 used with three screws per implant. The MAGNIFY®-S Spacer is to be filled with autograft bone and/or allogenic bone graft composed of cancellous and/or corticocancellous bone.

MONUMENT® Spacers
The MONUMENT® Spacer is an interbody fusion device 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), deformity (degenerative scoliosis or kyphosis), spinal stenosis, and failed previous fusion (pseudarthrosis). In addition, these patients may have up to Grade 1 spondylolisthesis or retrolisthesis at the

involved level(s). 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 MONUMENT® Spacer is to be used with four screws that accompany the implant. These devices are intended for use with supplemental fixation (e.g. facet screws or posterior fixation). The MONUMENT® Spacer is to be filled with autograft bone and/or allogenic bone graft composed of cancellous and/or corticocancellous bone.

InterContinental® Plate-Spacer

InterContinental® Plate-Spacers are lateral 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. All InterContinental® TPS coated spacers are indicated for the same use as non-coated PEEK versions.

InterContinental® Plate-Spacers are intended to be used with or without two screws and/or anchors which accompany the implants. These devices are intended for use with supplemental fixation (e.g. facet screws or posterior fixation). InterContinental® Plate-Spacers are to be filled with autograft bone and/or allogenic bone graft composed of cancellous and/or corticocancellous bone.

ELSA® Spacers

The ELSA® Spacer is an interbody fusion device 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.

The ELSA® Spacer is intended to be used with or without two screws and/or anchors which accompany the implants. These devices are intended for use with supplemental fixation. Hyperlordotic (≥20°) implants must be used with the two screws and/or anchors and supplemental fixation in addition to the two screws and/or anchors. The ELSA® Spacer is to be filled with autograft and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone.

Performance Data:
Mechanical testing was conducted with the additional implants in accordance with the “Guidance for Industry and FDA Staff, Class II Special Controls Guidance Document: Intervertebral Fusion Device,” June 12, 2007, and expulsion to demonstrate substantial equivalence to the predicate spacers.

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 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.