October 15, 2022

DePuy Spine
% Justin Eggleton
Vice President, Spine Regulatory Affairs
MCRA LLC
803 7th St NW
Washington, District of Columbia 20001

Re: K222276
Trade/Device Name: CONDUIT™ Cages and FIBERGRAFT™ BG Putty
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: ODP, MAX, MQV
Dated: July 29, 2022
Received: July 29, 2022

Dear Justin Eggleton:

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,

For

Laura C. Rose, Ph.D.
Assistant Director
DHT6C: Division of Restorative, Repair,
and Trauma 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)*

K222276

Device Name

CONDUIT™ Cervical Cage

Indications for Use *(Describe)*

The CONDUIT™ Cervical Cages with a microscopic roughened surface and micro and nano-scale features 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 - Tl. The CONDUIT™ Cervical Cages are also to be used with supplemental fixation systems that have been cleared for use in the cervical spine. CONDUIT™ Cervical Cages are designed for use with autogenous and/or allogeneic bone graft comprised of cancellous, and/or corticocancellous bone graft, or a bone void filler as cleared by 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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

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)*
K222276

Device Name
CONDUIT™ ALIF Cage

Indications for Use *(Describe)*
The CONDUIT™ ALIF Cages with a microscopic roughened surface and micro and nano-scale features in combination with supplemental fixation are indicated for use with autogenous and/or allogeneic bone graft comprised of cancellous, and/or corticocancellous bone graft, or a bone void filler as cleared by FDA for use in intervertebral body fusion to facilitate fusion in patients with degenerative disc disease (DDD) at one or two contiguous spinal levels from L2 - S 1 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.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

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)*
K222276

Device Name
CONDUIT™ TLIF Cage

Indications for Use *(Describe)*
The CONDUIT™ TLIF Cages with a microscopic roughened surface and micro and nano-scale features in combination with supplemental fixation are indicated for use with autogenous and/or allogeneic bone graft comprised of cancellous, and/or corticocancellous bone graft, or a bone void filler as cleared by FDA for use in intervertebral body fusion to facilitate fusion 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 non-operative treatment prior to treatment with the devices.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

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)*
K222276

Device Name
CONDUIT™ LLIF Cage

Indications for Use *(Describe)*
The CONDUIT™ LLIF Cages with a microscopic roughened surface and micro and nano-scale features is indicated for intervertebral body fusion procedures in skeletally mature patients with degenerative disc disease (DDD) at one or two contiguous levels from L2-S1. DDD is defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies. These DDD patients may also have up to Grade 1 spondylolisthesis or retrolisthesis at the involved level(s). These spinal implants are to be used with autogenous bone graft and/or allogeneic bone graft comprised of cancellous and/or corticocancellous bone graft, or a bone void filler as cleared by FDA for use in intervertebral body fusion to facilitate fusion. CONDUIT™ LLIF Cage is to be used with supplemental fixation. Patients should have at least six (6) months of non-operative treatment prior to treatment with an intervertebral cage.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

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)*
K222276

Device Name
CONDUIT™ T/PLIF Cage

Indications for Use *(Describe)*

The CONDUIT™ T/PLIF Cages with a microscopic roughened surface and micro and nano-scale features in combination with supplemental fixation are indicated for use with autogenous and/or allogeneic bone graft comprised of cancellous, and/or corticocancellous bone graft, or a bone void filler as cleared by FDA for use in intervertebral body fusion to facilitate fusion in patients with degenerative disc disease (DDD) at one or two contiguous spinal levels from L2 - S 1 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 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.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

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)*

K222276

Device Name

FIBERGRAFT™ BG Putty

Indications for Use *(Describe)*

FIBERGRAFT™ BG Putty - Bone Graft Substitute is indicated only for bony voids or gaps that are not intrinsic to the stability of the bony structure. FIBERGRAFT™ BG Putty is indicated to be gently packed into bony voids or gaps of the skeletal system (i.e., posterolateral spine, intervertebral disc space, extremities and pelvis). These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone. The product provides a bone void filler that resorbs and is replaced with bone during the healing process. FIBERGRAFT™ BG Putty must be used with autograft in the posterolateral spine. When used in intervertebral body fusion procedures, FIBERGRAFT™ BG Putty must be used on its own with an intervertebral body fusion device cleared by FDA for use with a bone void filler.

FIBERGRAFT™ BG Putty is not indicated for use in load-bearing applications; therefore, standard internal or external stabilization techniques must be followed to obtain rigid stabilization.

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

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K222276

Device Name
FIBERGRAFT™ BG Putty GPS

Indications for Use *(Describe)*
FIBERGRAFT™ BG Putty GPS - Bone Graft Substitute is indicated only for bony voids or gaps that are not intrinsic to the stability of the bony structure. FIBERGRAFT™ BG Putty GPS is indicated to be gently packed into bony voids or gaps of the skeletal system (i.e., posterolateral spine, intervertebral disc space, extremities and pelvis). These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone. The product provides a bone void filler that resorbs and is replaced with bone during the healing process. FIBERGRAFT™ BG Putty GPS must be used with autograft in the posterolateral spine. When used in intervertebral body fusion procedures, FIBERGRAFT™ BG Putty GPS must be used on its own with an intervertebral body fusion device cleared by FDA for use with a bone void filler.

FIBERGRAFT™ BG Putty GPS is not indicated for use in load-bearing applications; therefore, standard internal or external stabilization techniques must be followed to obtain rigid stabilization.

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

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K222276

Device Name
FIBERGRAFT™ BG Putty GPS Cannula

Indications for Use *(Describe)*
The GPS Cannula is intended for use only with FIBERGRAFT™ BG Putty GPS and no other products.

Type of Use *(Select one or both, as applicable)*

[x] 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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) SUMMARY

A. Submitter Information

Manufacturer:
Medos International SARL
Chemin-Blanc 38
2400 Le Locle, Switzerland

Submitter:
DePuy Synthes Spine
325 Paramount Drive
Raynham, MA 02767

Contact Person:
Mr. Justin Eggleton
Vice President, Spine Regulatory Affairs
MCRA LLC
jeggleton@mcra.com

Alternate Contact:
Philip Desjardins
Vice President, Global Regulatory Affairs
DePuy Synthes Spine
325 Paramount Drive
Raynham, MA 02767
pdesjard@its.jnj.com

B. Date Prepared September 28, 2022

C. Device Name - CONDUIT™ Cages

Trade/Proprietary Name: CONDUIT™ Cages

Common/Usual Name: Intervertebral body fusion device

Regulatory Class: Class II per 21 CFR §888.3080

Review Panel: Orthopedic

Product Codes: ODP, MAX

D. Device Name - FIBERGRAFT™ BG Putty

Trade/Proprietary Name: FIBERGRAFT™ BG Putty

Common/Usual Name: Resorbable calcium salt bone void filler device

Regulatory Class: Class II per 21 CFR §888.3045

Review Panel: Orthopedic

Product Codes: MQV

E. Predicate Device Names

Primary Predicate: DePuy Synthes Spine, K201605, EIT Cellular Cervical Cage, EIT Cellular ALIF Cage, EIT Cellular Titanium TLIF Cage, EIT Cellular Titanium LLIF Cage, EIT Cellular Titanium T/PLIF Cage

Additional Predicate: Nuvasive Inc., K203714, NuVasive Thoracolumbar Interbody Systems and NuVasive Attrax Putty

Additional Predicate: Prosidyan Inc., K170306, FIBERGRAFT™ BG Putty Bone Graft Substitute

F. Device Description

The CONDUIT™ Technology platform is a comprehensive portfolio of 3D-printed porous titanium interbody devices intended to stabilize the spinal segment, restore intervertebral height and to facilitate interbody fusion in the cervical (C2-T1) and lumbar spine (L2-S1). Designed to treat cervical and lumbar degenerative disc disease, the platform consists of the Cervical, Transforaminal (TLIF), Lateral (LLIF), Anterior (ALIF) and Transforaminal/Posterior Lumbar (T/PLIF) systems. Each system features a full breadth of sizes, footprints, heights and angles. The devices are intended to be used with supplemental spinal fixation, either applied anterior or posterior (e.g. using posterior pedicle screws, anterior plate system or anterior screw and rod system).

The CONDUIT™ Cages are made from Ti-6A1-4V ELI conforming to ASTM F3001 with an additive manufacturing process (Selective Laser Melting). The design contains solid structures and porous structures. The hollow geometry of the implants allows them to be packed with autogenous, or allogeneic bone graft comprised of cancellous and/or corticocancellous bone graft, or a bone void filler as cleared by FDA for use in intervertebral body fusion.

The 3D Printed CONDUIT™ Cages have a microscopic roughened surface with micro and nano-scale features. The micro and nano features are on all surfaces of the cage, including the superior, inferior, and peripheral surfaces, as well as each member of the internal cell structure.

The FIBERGRAFT™ BG Putty is an osteoconductive, resorbable, biocompatible bone graft substitute to be gently packed into defect sites and to be used as non-structural scaffolds. The FIBERGRAFT™ BG putty is made from 45S5 bioactive glass, where the bioactive glass components are mixed with an absorbable/polymeric carrier to form a cohesive material.

The purpose of this submission is to expand the indications for use of the CONDUIT™ Cages to include its use with FIBERGRAFT™ BG Putty. Additionally, the indications for the ALIF, TLIF, and T/PLIF cages are being expanded to include the use of allogeneic bone graft comprised of cancellous, and/or corticocancellous bone graft.

G. Indications for Use

CONDUIT™ Cervical Cage

The CONDUIT™ Cervical Cages with a microscopic roughened surface and micro and nano-scale features 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 CONDUIT™ Cervical Cages are also to be used with supplemental fixation systems that have been cleared for use in the cervical spine. CONDUIT™ Cervical Cages are designed for use with autogenous and/or allogeneic bone graft comprised of cancellous, and/or corticocancellous bone graft, or a bone void filler as cleared by FDA for use in intervertebral body fusion to facilitate fusion.

CONDUIT™ ALIF Cage

The CONDUIT™ ALIF Cages with a microscopic roughened surface and micro and nano-scale features in combination with supplemental fixation are indicated for use with autogenous and/or allogeneic bone graft comprised of cancellous, and/or corticocancellous bone graft, or a bone void filler as cleared by FDA for use in intervertebral body fusion to facilitate fusion 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.

CONDUIT™ TLIF Cage

The CONDUIT™ TLIF Cages with a microscopic roughened surface and micro and nano-scale features in combination with supplemental fixation are indicated for use with autogenous and/or allogeneic bone graft comprised of cancellous, and/or corticocancellous bone graft, or a bone void filler as cleared by FDA for use in intervertebral body fusion to facilitate fusion 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 non-operative treatment prior to treatment with the devices.

CONDUIT™ LLIF Cage

The CONDUIT™ LLIF Cages with a microscopic roughened surface and micro and nano- scale features is indicated for intervertebral body fusion procedures in skeletally mature patients with degenerative disc disease (DDD) at one or two contiguous levels from L2-S1. DDD is defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies. These DDD patients may also have up to Grade 1 spondylolisthesis or retrolisthesis at the involved level(s). These spinal implants are to be used with autogenous bone graft and/or allogeneic bone graft comprised of cancellous and/or corticocancellous bone graft, or a bone void filler as cleared by FDA for use in intervertebral body fusion to facilitate fusion. CONDUIT™ LLIF Cage is to be used with supplemental fixation. Patients should have at least six (6) months of non-operative treatment prior to treatment with an intervertebral cage.

CONDUIT™ T/PLIF Cage

The CONDUIT™ T/PLIF Cages with a microscopic roughened surface and micro and nano-scale features in combination with supplemental fixation are indicated for use with autogenous and/or allogeneic bone graft comprised of cancellous, and/or corticocancellous bone graft, or a bone void filler as cleared by FDA for use in intervertebral body fusion to facilitate fusion 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 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.

FIBERGRAFT™ BG Putty

FIBERGRAFT™ BG Putty - Bone Graft Substitute is indicated only for bony voids or gaps that are not intrinsic to the stability of the bony structure. FIBERGRAFT BG Putty is indicated to be gently packed into bony voids or gaps of the skeletal system (i.e., posterolateral spine, intervertebral disc space, extremities and pelvis). These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone. The product provides a bone void filler that resorbs and is replaced with bone during the healing process. FIBERGRAFT BG Putty must be used with autograft in the posterolateral spine. When used in intervertebral body fusion procedures, FIBERGRAFT BG Putty must be used on its own with an intervertebral body fusion device cleared by FDA for use with a bone void filler.

FIBERGRAFT BG Putty is not indicated for use in load-bearing applications; therefore, standard

internal or external stabilization techniques must be followed to obtain rigid stabilization.

FIBERGRAFT™ BG Putty GPS

FIBERGRAFT™ BG Putty GPS - Bone Graft Substitute is indicated only for bony voids or gaps that are not intrinsic to the stability of the bony structure. FIBERGRAFT BG Putty GPS is indicated to be gently packed into bony voids or gaps of the skeletal system (i.e., posterolateral spine, intervertebral disc space, extremities and pelvis). These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone. The product provides a bone void filler that resorbs and is replaced with bone during the healing process. FIBERGRAFT BG Putty GPS must be used with autograft in the posterolateral spine. When used in intervertebral body fusion procedures, FIBERGRAFT BG Putty GPS must be used on its own with an intervertebral body fusion device cleared by FDA for use with a bone void filler.

FIBERGRAFT BG Putty GPS is not indicated for use in load-bearing applications; therefore, standard internal or external stabilization techniques must be followed to obtain rigid stabilization.

FIBERGRAFT™ GPS Cannula

The GPS Cannula is intended for use only with FIBERGRAFT™ BG Putty GPS and no other products.

H. Summary of Similarities and Differences in Technological Characteristics, Performance, and Intended Use

The purpose of this Traditional 510(k) is to expand the indications for use of the CONDUIT™ Cages to include its used with FIBERGRAFT™ BG Putty. Additionally, the indications for the ALIF, TLIF, and T/PLIF cages are being expanded to include the use of allogeneic bone graft comprised of cancellous, and/or corticocancellous bone graft. The subject device is substantially equivalent to the predicate devices with respect to indications, design, function, and performance. There are no differences in technological characteristics that will raise new concerns of safety or performance.

I. Materials

The CONDUIT™ Cervical and Lumbar Cages are all constructed from Standard Specification for Additive Manufacturing Titanium-6 Aluminum-4 Vanadium ELI with Extra Low Interstitials components using full-melt powder bed fusion in conformance with ASTM F3001. The BG Putty is composed of the same bioactive glass material with the same bioactive glass chemical composition and the same type and duration of patient contact as the predicate. The materials and manufacturing process for the CONDUIT™ subject devices are identical to that of the predicate device. Similarly, the materials and composition of the BG Putty device are identical to that of the predicate device and the manufacturing process remains substantially the same as that of the predicate. It is important to note that the manufacturing location of BG Putty was moved from Steris to Prosidyan (now DePuy Synthes), however the process has not changed.

J. Performance Data

The performance of the CONDUIT™ Cervical and Lumbar Cages and the FIBERGRAFT™ BG Putty have been assessed individually within their respective submissions (K201605, and K170306). Clinical data has been utilized to demonstrate the performance and safety of the expanded indications for use, which includes the use of the CONDUIT™ Cages with FIBERGRAFT™ BG Putty. The clinical data includes radiographic and clinical outcomes from a retrospective study and two investigator-initiated studies. The data provided includes 178 subjects and was collected from multiple sites across the United States (CA, TX, FL) to capture a variety of populations with diverse gender and racial/ethnic backgrounds that is representative of the intended users of the subject devices. The results of the data support the performance of the subject devices in intervertebral body fusion based on fusion and adverse event rates. Additional rationales were provided to justify the expanded indications based upon the clinical data results.

K. Conclusion

Based on the body of data presented throughout the submission, it has been determined that the subject devices are substantially equivalent to the predicate devices with respect to indications for use, technological characteristics, and performance data.