January 15, 2019

Zimmer Biomet Spine, Inc.
Mr. Alex Pawlowski
Regulatory Affairs Specialist
10225 Westmoor Drive
Westminster, Colorado 80021

Re: K181096
Trade/Device Name: Avenue® P Cage System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: OVD, MAX
Dated: December 14, 2018
Received: December 18, 2018

Dear Mr. Pawlowski:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Melissa Hall -S

For Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
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)*
K181096

Device Name
Avenue® P Cage System

Indications for Use *(Describe)*
Avenue P is indicated for intervertebral body fusion of the lumbar spine, from L2 to S1, in skeletally mature patients who have had six months of non-operative treatment. The device is intended for use at either one level or two contiguous levels for the treatment of degenerative disc disease (DDD). DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. DDD patients may also have up to Grade 1 spondylolisthesis or retrolisthesis at the involved levels.

The device is implanted via a transforaminal or posterior approach and intended for use with autograft and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft. Avenue P is designed for use with or without integrated fixation and must be used in conjunction with posterior supplemental fixation cleared for use as an adjunct to fusion in the lumbar spine.

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."

510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR § 807.92.

Preparation Date	April 25, 2018
Applicant/Sponsor	Zimmer Biomet Spine, Inc. 10225 Westmoor Dr. Westminster, CO 80021
Contact Person	Alex Pawlowski Regulatory Affairs Specialist Phone: 303-533-1062 Fax: 303-465-5522
Trade Name	Avenue® P Cage System
Common Name	Intervertebral body fusion device
Device Class	Class II
Classification Name	OVD – Intervertebral Body Fusion Device With Integrated Fixation, Lumbar (21 CFR 888.3080) MAX – Intervertebral Body Fusion Device With Bone Graft, Lumbar (21 CFR 888.3080)
Device Panel	Orthopedic

Device Description & Technological Characteristics:

The Avenue® P Cage System consists of various sized, titanium coated, PEEK intervertebral body fusion cages, titanium anchoring plates for integrated fixation, and associated instrumentation. The system is intended to be used to stabilize lumbosacral spinal segments, promote spinal fusion in combination with bone graft and to restrict motion at the implanted vertebral level.

The Avenue® P cages have been designed for use with optional VerteBRIDGE® integrated fixation anchoring plates. Upon insertion, the VerteBRIDGE® anchoring plate provides and maintains additional stability and expulsion resistance by direct purchase into the bony vertebral endplates.

The base material of the Avenue® P Cage System implant is polyetheretherketone (PEEK-OPTIMA LT1) which conforms to ASTM F2026-12. This PEEK base is coated on the superior and inferior surfaces with a plasma sprayed, commercially pure titanium (SPONDYCOAT-T 371A) conforming to ASTM F1580-12.

Intended Use / Indications for Use:

Avenue P is indicated for intervertebral body fusion of the lumbar spine, from L2 to S1, in skeletally mature patients who have had six months of non-operative treatment. The device is intended for use at either one level or two contiguous levels for the treatment of degenerative disc disease (DDD). DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. DDD patients may also have up to Grade 1 spondylolisthesis or retrolisthesis at the involved levels.

The device is implanted via a transforaminal or posterior approach and intended for use with autograft and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft. Avenue P is designed for use with or without integrated fixation and must be used in conjunction with posterior supplemental fixation cleared for use as an adjunct to fusion in the lumbar spine.

Summary of Technological Characteristics:

The technological characteristics of the subject Avenue® P cage system components remain the same as, or similar to, the primary predicate, CONCORDE® Bullet (K151773), and the additional predicates, Lucent Ti-Bond Systems (K150061), Biomet Spine Fusion System (K153695), Avenue T TLIF Cage (K142645) and ROI-C Titanium-Coated Implant System (K151934) in regards to intended use, indications for use, design, manufacturing methods, fundamental technology, and operational principles. The purpose of this submission is to seek clearance for the Avenue® P Cage System.

Summary of Performance Data:

To support substantial equivalence, mechanical testing of the intervertebral body fusion implants of the subject Avenue P Cage System were assessed and tested appropriately in accordance with ASTM standards. The assessment concluded that intervertebral body fusion device are substantially equivalent to the identified predicates for use with FDA's Guidance for Industry and FDA Staff – Spinal System 510(k)s dated May 3, 2004 and Class II Special Controls Guidance Document: Intervertebral Body Fusion Device dated June 12, 2007. Performance testing included assessments per ASTM F2077 (axial compression, compression shear, and torsion). MR Safety testing was conducted per ASTM F2052 (Displacement Force), ASTM F2213 (Torque), ASTM F2119 (Image Artifact), and ASTM F2182 (RF heating). In all instances, the modified device functioned as intended and demonstrated substantial equivalence to the predicate devices.

Substantial Equivalence:

The subject Avenue® P Cage System implants have the same intended use, indications, technological characteristics, and principles of operation as the previously cleared CONCORDE® Bullet (K151773), Lucent® Ti-Bond Systems (K150061), Biomet Spine Fusion System (K153695), Avenue T TLIF Cage (K142645) and ROI-C Titanium-Coated Implant System (K151934). Additionally, the subject Avenue® P Cage System and it's predicates are regulated under 21 CFR 888.3080. The subject Avenue® P components do not raise any new issues of safety or effectiveness when compared to the cited predicates. Performance data presented also demonstrated comparable properties to the previously cleared devices.

Conclusion:

The Avenue® P Cage System is substantially equivalent to the predicate system as a spinal fixation device in regards to intended use, indications for use, fundamental technology including design, materials, manufacturing methods, sterility, and operational principles. Furthermore, mechanical testing and other supporting information sufficiently demonstrate the substantial equivalence of the subject components to the CONCORDE® Bullet, Lucent Ti-Bond, Biomet Spine Fusion, Avenue T TLIF Cage and ROI-C Titanium-Coated Implant Systems which have been cleared for intervertebral body fusion. Based on this information, the subject device does not raise any new issues regarding the safety or efficacy when compared to its predicates.