DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

July 15, 2016

Stryker Spine
Ms. Tina Mornak
Regulatory Affairs Specialist
2 Pearl Court
Allendale, New Jersey 07401

Re: K161407
Trade/Device Name: Ascential IBD PEEK^{C} Spacer
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: ODP
Dated: June 23, 2016
Received: June 24, 2016

Dear Ms. Mornak:

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. 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 Parts 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson -S

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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K161407

Device Name
Ascential IBD PEEKc Spacer

Indications for Use *(Describe)*
The Ascential IBD PEEKc Spacers are indicated for use in cervical interbody fusion procedures in skeletally mature patients with degenerative disc disease (DDD) at one level from the C2-C3 disc to the C7-T1 disc. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The Ascential IBD PEEKc Spacers are to be used with autogenous bone and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft, and are to be implanted via an open, anterior approach.

The Ascential IBD PEEKc Spacer is intended to be used with supplemental fixation systems that have been cleared for use in the cervical spine. This cervical device is to be used in patients who have had six weeks of non-operative treatment.

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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510(k) Summary: Ascential IBD PEEK^{C} Spacer	
Submitter:	Stryker Spine 2 Pearl Court Allendale, New Jersey 07401
Contact Person	Tina Mornak Regulatory Affairs Specialist Phone: 201-760-8193 Fax: 201-962-4070 Email: tina.mornak@stryker.com
Date Prepared	May 11, 2016
Trade Name	Ascential IBD PEEK^{C} Spacer
Common Name	Cervical Interbody Device
Proposed Class	Class II
Classification Name and Number	Intervertebral body fixation device 21 CFR §888.3080
Product Code	ODP
Predicate Devices	Primary Predicate: AVS® AS PEEK Spacer (K142251)
Device Description	The Ascential IBD PEEK^{C} Spacer is a hollow, ring-shaped PEEK Optima® LT1 implant with three Tantalum marker pins. The spacers are offered in a variety of lengths, heights, and lordotic angles to adapt to varying patient anatomies. The hollow, ring-shaped implants have serrations on the top and bottom surfaces of the spacer. The hollow space of the implant is intended to hold bone graft material. The IBD PEEK^{C} spacer is to be used as an interbody fusion device (IBD) for the cervical spine (from C2-C3 to C7-T1). The Ascential IBD PEEK^{C} Spacers to be used for cervical IBD applications are available in a variety of sizes, from 4 mm to 12 mm in height (in 1 mm increments), two depths: 12 mm and 14 mm and two widths: 14 mm and 16 mm. There are also 0° and 4° wedge shaped options that allow the surgeon to choose the size better suited to the patient's anatomy and pathology. Class I instruments are provided for successfully performing anterior cervical interbody fusion procedures. The Ascential IBD PEEK^{C} Spacer is a sterile version (gamma sterilized) of the AVS® AS PEEK Spacer
Intended Use	The Ascential IBD PEEK^{C} spacers are indicated for use in cervical interbody fusion procedures in skeletally mature patients with degenerative disc disease (DDD) at one level from the C2-C3 disc to the C7-T1 disc. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The Ascential IBD PEEK^{C} spacers are to be used with autogenous bone graft and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft, and are to be implanted via an open, anterior approach. The Ascential IBD PEEK^{C} spacers are intended to be used with supplemental fixation systems that have been cleared for use in the cervical spine. This cervical device is to be used in patients who have had six weeks of non-operative treatment.

510(k) Summary: Ascential IBD PEEK^{C} Spacer	
Summary of the Technological Characteristics	The subject sterile packed implants have the same technological characteristics as the non-sterile packed predicate devices. These characteristics include same design, technical requirements, materials of construction, and indications/ intended use. Design modifications were not incorporated to facilitate sterile packaging of the implants.
Summary of the Performance Data	The sterilized material of IBD PEEK^{C} has mechanically equivalent material properties to the non-sterile AVS AS implants. Therefore, verification testing conducted for AVS AS is appropriate for the IBD PEEK^{C} implants as they are dimensionally identical. Supporting documentation from Invibio shows of the effects of up to 75kGY gamma sterilization of PEEK-OPTIMA® material, gamma sterilization does not impact mechanical performance of the material. Bacterial endotoxin testing (BET) as specified in ANSI/AAMI ST72:2011 is used for pyrogenicity testing to achieve the Endotoxin limit of < 20EU/Device.
Conclusions	The subject implants that are intended to be sterile packed are substantially equivalent to the predicate non-sterile devices. The subject implants retain the same intended and indications for use, technological characteristics, and mode of operation as the predicate non-sterile implants. The accelerated aging data demonstrated that the sterilization process and sterile barrier packaging system are effective in maintaining sterility for the recommended 5 year shelf-life.