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

August 12, 2015

Biomet Spine
Ms. Alexandra Beck
Regulatory Affairs Specialist
310 Interlocken Parkway, Suite 120
Broomfield, Colorado 80021

Re: K151064
Trade/Device Name: Solitaire®-C Cervical Spacer System, C-Thru™ Anterior Spinal System, and Breckenridge® Small Intervertebral Body Fusion System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: OVE, ODP
Dated: July 10, 2015
Received: July 13, 2015

Dear Ms. Beck:

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 Part 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)*
K151064

Device Name
Breckenridge® Small Intervertebral Body Fusion System

Indications for Use *(Describe)*

When used as a cervical intervertebral body fusion device, the Breckenridge implant is intended for spinal fusion procedures to be used with autogenous and/or allogeneic bone graft comprised of cancellous and/or corticocancellous bone graft to facilitate fusion in skeletally mature patients with degenerative disc disease ("DDD") at one spinal level from the C2-C3 disc to the C7-T1 disc. DDD is defined as neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. These patients should have had at least six weeks of non-operative treatment. The Breckenridge device is to be implanted via an anterior approach and is to be combined with supplemental fixation. Approved supplemental fixation systems include the Biomet Anterior Cervical Plate System.

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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Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K151064

Device Name
C-Thru™ Anterior Spinal System

Indications for Use *(Describe)*

When used as a cervical intervertebral fusion device, the C-Thru™ Anterior Spinal System is intended for spinal fusion procedures at one level (C2 to T1) in skeletally mature patients with degenerative disc disease (DDD) of the cervical spine. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. These patients should have had six months of non-operative treatment. The C-Thru™ Spacers are intended for use with supplemental fixation and autogenous and/or allogeneic bone graft comprised of cancellous and/or corticocancellous bone graft to facilitate the 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.

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)*
K151064

Device Name
Solitaire®-C Cervical Spacer System

Indications for Use *(Describe)*

The Solitaire®-C Cervical Spacer System is indicated for stand-alone anterior cervical interbody fusion procedures in skeletally mature patients with cervical degenerative disc disease at one level from C2 to T1. Cervical degenerative 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. The Solitaire®-C Cervical Spacer System is to be used with autograft and/or allogeneic bone graft comprised of cancellous and/or corticocancellous bone graft to facilitate fusion and implanted via an anterior approach. The Solitaire-C spacer must be implanted with the Solitaire-C titanium screws that are part of the system. 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.

510(k) Summary

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

Preparation Date:	07August2015
Applicant/Sponsor:	Biomet Spine 310 Interlocken Parkway, Suite 120 Broomfield, CO 80021
Contact Person:	Alexandra Beck Regulatory Affairs Specialist Phone: 303-501-8397 Fax: 303-501-8444
Trade name:	**Solitaire®-C Cervical Spacer System**
Common Name:	Cervical interbody fusion device with integrated fixation
Classification Name (Product Code):	Intervertebral Fusion Device with Integrated Fixation, Cervical (OVE)
Device Panel - Regulation No.:	Orthopedic - 21 CFR § 888.3080
Trade name:	**C-Thru™ Anterior Spinal System**
Common Name:	Cervical and non-cervical spinal spacer
Classification Name (Product Code):	Intervertebral Fusion Device with Bone Graft, Cervical (ODP)
Device Panel - Regulation No.:	Orthopedic - 21 CFR § 888.3080
Trade name:	**Breckenridge® Small Intervertebral Body Fusion System**
Common Name:	Biomet Intervertebral Body Fusion Device
Classification Name (Product Code):	Intervertebral Fusion Device with Bone Graft, Cervical (ODP)
Device Panel - Regulation No.:	Orthopedic - 21 CFR § 888.3080
Primary Predicate:	CONSTRUX Mini PEEK Spacer System (K142152)
Other Predicates:	Solitaire®-C Cervical Spacer System (K113796) C-Thru™ Anterior Spinal System (K092336) Breckenridge® Small Intervertebral Body Fusion System (K103660)

Device Description:
The cervical intervertebral body PEEK spacers have a hollowed cut-out central area to accommodate autogenous and/or allogeneic bone graft. Furthermore, the upper and lower surfaces have a series of transverse slots or grooves to improve stability and fixation once the device is inserted. All implants in these systems are made of PEEK-OPTIMA®, tantalum, and titanium alloy (Ti-6Al-4V ELI). The

spacer body, plates and screws are available in a variety of sizes and configurations to accommodate anatomical variation in different vertebral levels and/or patient anatomy. The Solitaire-C spacer is a stand-alone device that must be implanted with the Solitaire-C titanium screws that are part of the system.

The Solitaire®-C Cervical Spacer System and C-Thru™ Anterior Spinal System implants are offered in sterile packed versions while the Breckenridge® Small Intervertebral Body Fusion System is packaged non-sterile, to be sterilized by the end user.

This Traditional 510(k) is being submitted to seek clearance for the addition of allograft (cancellous and/or corticocancellous bone graft) indications to the aforementioned cervical intervertebral body PEEK spacer systems (both stand-alone devices and devices which require supplemental fixation).

Indications for Use:

Solitaire®-C Cervical Spacer System

The Solitaire®-C Cervical Spacer System is indicated for stand-alone anterior cervical interbody fusion procedures in skeletally mature patients with cervical degenerative disc disease at one level from C2 to T1. Cervical degenerative 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. The Solitaire®-C Cervical Spacer System is to be used with autograft and/or allogeneic bone graft comprised of cancellous and/or corticocancellous bone graft to facilitate fusion and implanted via an anterior approach. The Solitaire-C spacer must be implanted with the Solitaire-C titanium screws that are part of the system. This cervical device is to be used in patients who have had six weeks of non-operative treatment.

C-Thru™ Anterior Spinal System

When used as a cervical intervertebral fusion device, the C-Thru™ Anterior Spinal System is intended for spinal fusion procedures at one level (C2 to T1) in skeletally mature patients with degenerative disc disease (DDD) of the cervical spine. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. These patients should have had six months of non-operative treatment. The C-Thru™ Spacers are intended for use with supplemental fixation and autogenous and/or allogeneic bone graft comprised of cancellous and/or corticocancellous bone graft to facilitate the fusion.

Breckenridge® Small Intervertebral Body Fusion system

When used as a cervical intervertebral body fusion device, the Breckenridge implant is intended for spinal fusion procedures to be used with autogenous and/or allogeneic bone graft comprised of cancellous and/or corticocancellous bone graft to facilitate fusion in skeletally mature patients with degenerative disc disease (“DDD”) at one spinal level from the C2-C3 disc to the C7-T1 disc. DDD is defined as neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. These patients should have had at least six weeks of non-operative treatment. The Breckenridge device is to be implanted via an anterior approach and is to be combined with supplemental fixation. Approved supplemental fixation systems include the Biomet Anterior Cervical Plate System.

Summary of Technologies:

As established in this submission, the subject systems are substantially equivalent to other predicate devices cleared by the FDA for commercial distribution in the United States. The subject devices were shown to be substantially equivalent and have the same technological characteristics to the predicate devices through comparison in areas including design, intended use, material composition, and function. These devices do not contain software or electrical equipment.

Performance Data – Summary of Non-Clinical Test Conducted for Determination of Substantial Equivalence

The changes proposed did not require non-clinical testing in order to demonstrate substantial equivalence to the predicate devices.

Performance Data – Summary of Clinical Test Conducted for Determination of Substantial Equivalence

Published retrospective clinical data for cervical interbody fusion devices similar to the subject devices was completed to support this Premarket Notification. The published clinical outcomes demonstrated that the use of allograft (cancellous and/or corticocancellous bone graft) in anterior cervical interbody fusion poses no new risks to patients. No changes were made to the existing devices; therefore, no additional testing was required or performed.

Substantial Equivalence:

The devices included in this submission have the same or similar intended uses, indications, technological characteristics, and principles of operation as the previously cleared CONSTRUX Mini PEEK Spacer System (K142152). Thus, the subject devices with expanded indications to include allograft (cancellous and/or corticocancellous bone graft) are substantially equivalent to the predicate devices.

Conclusion:

In summary, the expanded indications for the Solitaire®-C Cervical Spacer System, C-Thru™ Anterior Spinal System, and Breckenridge® Small Intervertebral Body Fusion System have the same or similar: intended use, indications for use, technological characteristics, principles of operation and performances as the previously cleared CONSTRUX Mini PEEK Spacer System (K142152). A retrospective evaluation of clinical literature demonstrates that expanding the indications of the above mentioned systems does not raise new questions of safety and efficacy and that the subject systems are substantially equivalent to the previously cleared CONSTRUX Mini PEEK Spacer System (K142152).