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 8, 2016

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

Re: K152622
Trade/Device Name: Alta ACDF System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: OVE
Dated: June 3, 2016
Received: June 16, 2016

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 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)*

K152622

Device Name
Alta ACDF System

Indications for Use *(Describe)*

The Alta ACDF System is a stand-alone cervical fusion device intended for use in skeletally mature patients with degenerative disc disease (DDD) of the cervical spine (C3-T1) at one level. DDD is defined as discogenic 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) weeks of non-operative treatment. The Alta ACDF System is to be filled with autogenous and/or allogeneic bone graft comprised of cancellous and/or corticocancellous bone graft material, and is to be used with titanium alloy screws which accompany the implant.

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:	11September2015
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:	Alta ACDF System
Common Name:	Intervertebral Body Fusion Device
Classification Name (Product Code):	Intervertebral Fusion Device with Integrated Fixation, Cervical (OVE) Class II per 21 CFR § 888.3080
Device Panel:	Orthopedic
Primary Predicate:	Solitaire®-C Cervical Spacer System, C-Thru™ Anterior Spinal System, and Breckenridge® Small Intervertebral Body Fusion System (K151064)
Additional Predicate:	Alta ACDF System (K112388)

Device Description:
The cervical intervertebral body PEEK spacers have a hollowed cut-out central area to accommodate autogenous and/or allogeneic bone graft and the upper and lower surfaces have a series of transverse slots or grooves to improve stability and fixation once the device is inserted. The implants in this system 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 Alta ACDF System is intended for stand-alone use in cervical intervertebral body fusion and must be used with the titanium alloy screws which accompany the implant.

This Traditional 510(k) is being submitted to seek clearance for the addition of allograft (cancellous and/or corticocancellous bone graft) indications to the Alta ACDF System.

Indications for Use:
The Alta ACDF System is a stand-alone cervical fusion device intended for use in skeletally mature patients with degenerative disc disease (DDD) of the cervical spine (C3-T1) at one level. DDD is defined as discogenic 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) weeks of non-operative treatment. The Alta ACDF System is to be filled with autogenous and/or allogeneic bone graft comprised of cancellous

and/or corticocancellous bone graft material, and is to be used with titanium alloy screws which accompany the implant.

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 device was shown to be substantially equivalent and have the same technological characteristics to the predicate devices cleared in K151064 through comparison in areas including design, intended use, material composition, and function. The Alta ACDF System does 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 device 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 are being made to the existing device as subject of this Premarket Notification, aside from the expanded indications; therefore, no additional testing was required or performed.

Substantial Equivalence:
The Alta ACDF System has the same or similar intended use, Indications for Use, technological characteristics, and principles of operation as the previously cleared Solitaire®-C Cervical Spacer System, C-Thru™ Anterior Spinal System, and Breckenridge® Small Intervertebral Body Fusion System (K151064). Thus, the subject device with expanded indications to include allograft (cancellous and/or corticocancellous bone graft) is substantially equivalent to the predicate devices.

Conclusion:
In summary, the expanded indications for the Alta ACDF System have the same or similar: intended use, Indications for Use, technological characteristics, principles of operation and performance as the previously cleared Solitaire®-C Cervical Spacer System, C-Thru™ Anterior Spinal System, and Breckenridge® Small Intervertebral Body Fusion System (K151064). A retrospective evaluation of clinical literature demonstrates that expanding the indications of the subject system does not raise new questions of safety and efficacy and that the subject system is substantially equivalent to the previously cleared Solitaire®-C Cervical Spacer System, C-Thru™ Anterior Spinal System, and Breckenridge® Small Intervertebral Body Fusion System (K151064).