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

November 5, 2014

Mr. Spencer Kimber
Regulatory Affairs Specialist
Biomet Spine, LLC
310 Interlocken Parkway, Suite 120
Broomfield, Colorado 80021

Re: K133518
Trade/Device Name: MaxAn® Anterior Cervical Plate System
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal intervertral body fixation orthosis
Regulatory Class: Class II
Product Code: KWQ
Dated: October 3, 2014
Received: October 6, 2014

Dear Mr. Kimber:

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

Biomet Spine
Traditional 510(k) Premarket Notification

Indications for Use

510(k) Number (if known): K133518

Device Name: MaxAn® Anterior Cervical Plate System

Indications for Use:

The MaxAn® Anterior Cervical Plate System is intended for anterior interbody fixation of the cervical spine. Indications for use include the temporary stabilization of the anterior spine during the development of cervical fusions in patients with degenerative disc disease (as defined by neck pain of discogenic origin confirmed by patient history and radiographic studies), trauma including fractures, tumors, deformity (defined as kyphosis, lordosis, or scoliosis), pseudarthroses, and/or failed previous fusions. The intended levels for treatment range from C2-T1.

Prescription Use **X** (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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(Division Sign-Off
Division of Orthopedic Devices
510(k) Number: K133518

510(k) Summary

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

Preparation Date:	October 3, 2014
Applicant/Sponsor:	Biomet Spine 399 Jefferson Road Parsippany, NJ 07054
Contact Person:	Spencer Kimber Regulatory Affairs Specialist Phone: 303-501-8523 Fax: 303-501-8444
Trade name:	MaxAn® Anterior Cervical Plate System
Common Name:	Spinal Intervertebral Body Fixation Orthosis
Classification Name (Product Code):	Appliance, Fixation, Spinal Intervertebral Body (KWQ)
Device Panel - Regulation No.:	Orthopedic - 21 CFR 888.3060
Primary Predicate:	K080646

Device Description:

The MaxAn® Anterior Cervical Plate System Cervical Plate System consists of titanium alloy plates and screws intended for use in anterior cervical discectomy and fusion (ACDF) procedures. Cervical plates are intended for use at 1-5 levels, and are available in lengths from 8mm-130mm. Screws are available in both fixed and variable versions in sizes 4.0mm and 4.5mm in various lengths. All components are available in both sterile and non-sterile configurations.

The purpose of this submission is to add MR Conditional labeling for the components of the MaxAn system.

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Summary of Technologies:

The technological characteristics of the MaxAn Anterior Cervical Plate System are unchanged from its original clearance in K080646 in regards to intended use, indications, design, materials, manufacturing methods, sterility, fundamental technology, and operational principles.

Performance Data:

MR compatibility testing was conducted according to the following ASTM standards:

- ASTM F2052-06
- ASTM F2119-07
- ASTM F2182-11a

Qualitative torque testing was presented.

Static compression bending, static torsion and dynamic compression tests were conducted according to ASTM F1717-04 Spinal Constructs in a Vertebrectomy Model.

Test results indicate that the MaxAn Cervical Plate System meets the ASTM recommendations for MR Conditional labeling in terms of device heating, magnetically induced displacement and MRI artifacts.

Substantial Equivalence:

The addition of MR Conditional Labeling does not alter the substantial equivalence of the MaxAn Cervical Plate System, which was previously cleared in K080646.

Conclusion:

The non-clinical testing provided in this submission supports the addition of MR Conditional labeling for the MaxAn Cervical Plate System. Based upon the testing provided, and the additional labeling, the subject device is as safe and effective as the predicate device.