



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

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

February 4, 2016

Re: K151224  
Trade/Device Name: Lineum OCT Spine System  
Regulatory Class: Unclassified  
Product Code: NKG, KWP  
Dated: May 6, 2015  
Received: May 7, 2015

Dear Mr. Kimber:

This letter corrects our substantially equivalent letter of June 30, 2015.

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" (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 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

## Indications for Use

510(k) Number (if known)

K151224

Device Name

Lineum OCT Spine System

Indications for Use (Describe)

The Lineum OCT Spine System is intended to provide immobilization and stabilization of spinal segments as an adjunct to fusion for the following acute and chronic instabilities of the craniocervical junction, the cervical spine (C1 to C7) and the thoracic spine (T1-T3): traumatic spinal fractures and/or traumatic dislocations; instability or deformity; failed previous fusions (e.g. pseudarthrosis); tumors involving the cervical/thoracic spine; and degenerative disease, including intractable radiculopathy and/or myelopathy, neck and/or arm pain of discogenic origin as confirmed by radiographic studies, and degenerative disease of the facets with instability. The Lineum OCT Spine System is also intended to restore the integrity of the spinal column even in the absence of fusion for a limited time period in patients with advanced stage tumors involving the cervical spine in whom life expectancy is of insufficient duration to permit achievement of fusion.

In order to achieve additional levels of fixation, the Lineum OCT Spine System can also be connected to the Biomet Polaris System via transitional rods or using the Altius Rod Connectors or Polaris Dominoes. Please refer to the individual system's package insert for a list of indications for use for each 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)

### CONTINUE ON A SEPARATE PAGE IF NEEDED.

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## 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:** May 26, 2015

**Applicant/Sponsor:** Biomet Spine  
310Interlocken Parkway, Suite 120  
Broomfield, CO 80021

**Contact Person:** Spencer Kimber  
Regulatory Affairs Specialist  
Phone: 303-501-8523  
Fax: 303-501-8444

**Trade name:** Lineum OCT Spine System

**Common Name:** Occipito-cervico-thoracic spinal fixation system  
Spinal Interlaminar Fixation Orthosis  
Posterior Cervical System

**Classification** Posterior, Cervical Pedicle Screw Spine Fixation  
Orthopaedic and Rehabilitation Devices Panel  
Unclassified; Pre-Amendment Device  
Product Code: NKG

Appliance, Fixation, Spinal Interlaminar  
Orthopaedic and Rehabilitation Devices Panel  
Class 2 per 21 CFR 888.3050  
Product Code: KWP

**Primary Predicate:** Synapse Occipital-Cervical-Thoracic (OCT) System – K142838

**Reference Devices:** Integra Atoll – K083073  
Nextgen Altius OCT System – K113593  
Mountaineer OCT Spinal System – K080828

### Device Description:

The Lineum OCT Spine System consists of various screws, hooks, plates, rods, connectors, etc. that are used to build a construct to provide supplemental stabilization of spinal segments to support fusions. The system can be assembled in a variety of configurations, allowing the surgeon to tailor the construct to the particular needs of the patient. The implants are designed for the occiput, cervical, and/or upper thoracic spine (Occiput – T3) and consist of medical grade titanium alloy and CoCrMo alloy, similar to the predicate device.

### Intended Use/Indications for Use:

*The Lineum OCT Spine System is intended to provide immobilization and stabilization of spinal segments as an adjunct to fusion for the following acute and chronic instabilities of the craniocervical junction, the cervical spine (C1 to C7) and the thoracic spine (T1-T3): traumatic spinal fractures and/or traumatic dislocations; instability or deformity; failed previous fusions (e.g. pseudarthrosis); tumors involving the cervical/thoracic spine; and degenerative disease, including intractable radiculopathy and/or myelopathy, neck and/or arm pain of discogenic origin as confirmed by radiographic studies, and degenerative disease of the facets with instability. The Lineum OCT Spine System is also intended to restore the integrity of the spinal column even in the absence of fusion for a limited time period in patients with advanced stage tumors involving the cervical spine in whom life expectancy is of insufficient duration to permit achievement of fusion.*

*In order to achieve additional levels of fixation, the Lineum OCT Spine System can also be connected to the Biomet Polaris System via transitional rods or using the Altius Rod Connectors or Polaris Dominoes. Please refer to the individual system's package insert for a list of indications for use for each system.*

**Summary of Technologies:**

The technological characteristics of the new components are the same as, or similar to, the predicate devices in regards to design and operational principle. The new components do not alter the fundamental scientific technology of the device.

**Performance Data:**

Published literature and performance testing were provided to support the substantial equivalence of the modified Lineum OCT Spine System. The modified device functions as intended and the observed test results demonstrate that the device performs as well as or better than the unmodified system. The non-clinical tests performed (e.g. mechanical construct and component testing) were based on ASTM2706 and ASTM1798.

**Conclusion:**

The design features, materials used, indications for use, surgical approach, manufacturing methods and sterilization methods are substantially equivalent to the predicate device. The mechanical testing provided demonstrates the substantial equivalence of the subject Lineum OCT Spine System.