November 20, 2017

Aesculap® Implant Systems, Inc.
% Ms. Lisa M. Boyle
Manager, Regulatory Affairs
3773 Corporate Parkway
Center Valley, Pennsylvania 18034

Re: K172032
Trade/Device Name: Modulift Vertebral Body Replacement (VBR) System
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal intervertebral body fixation orthosis
Regulatory Class: Class II
Product Code: PLR, MQP
Dated: October 16, 2017
Received: October 18, 2017

Dear Ms. Boyle:

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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Ronald P. Jean -S for

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)*
K172032

Device Name
Modulift Vertebral Body Replacement (VBR) System

Indications for Use *(Describe)*
The Modulift VBR System is indicated for use in the cervical spine (C3-C7 vertebral bodies for the small VBR implant) and thoracolumbar spine (T1-L5 vertebral bodies for the small/medium/large VBR implant) in skeletally mature patients for partial or total replacement of a diseased, collapsed, damaged, or unstable vertebral body due to tumor, osteomyelitis, trauma (i.e. fracture), or for reconstruction following corpectomy performed to achieve decompression of the spinal cord and neural tissues in degenerative disorders.

The Modulift VBR System is intended for use with autograft or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft, as an adjunct to fusion. The Modulift VBR 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, thoracic, and lumbar spine in whom life expectancy is of insufficient duration to permit achievement of fusion, with bone graft used at the surgeon's discretion.

The Modulift VBR System is intended to be used with supplemental fixation systems that have been cleared by the FDA. When used in the thoracolumbar spine, the Modulift VBR System is intended for use with supplemental spinal fixation systems such as the Aesculap MACS TL or S4 Systems. When used in the Cervical Spine at one or two levels, the Modulift Vertebral Body Replacement (VBR) System is intended to be used with supplemental fixation systems (i.e., ABC Anterior Cervical System or the Quintex Cervical System). When used at more than two levels in the cervical spine, supplemental fixation should include posterior fixation that has been cleared by FDA (i.e., Aesculap S4 Cervical 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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4. 510(k) Summary

Device Trade Name: Modulift Vertebral Body Replacement (VBR) System

Manufacturer: Aesculap® Implant Systems, Inc.
3773 Corporate Parkway
Center Valley, PA 18034

Contact: Lisa M. Boyle
Manager, Regulatory Affairs
800-258-1946 x 5274
610-791-6882 (fax)

Date Prepared: November 16, 2017

Classifications: 21 CFR §888.3060, Spinal Intervertebral Body Fixation Orthosis

Class: II

Product Codes: PLR/MQP

Indications For Use:

The Modulift VBR System is indicated for use in the cervical spine (C3-C7 vertebral bodies for the small VBR implant) and thoracolumbar spine (T1-L5 vertebral bodies for the small/medium/large VBR implant) in skeletally mature patients for partial or total replacement of a diseased, collapsed, damaged, or unstable vertebral body due to tumor, osteomyelitis, trauma (i.e. fracture), or for reconstruction following corpectomy performed to achieve decompression of the spinal cord and neural tissues in degenerative disorders.

The Modulift VBR System is intended for use with autograft or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft, as an adjunct to fusion. The Modulift VBR 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, thoracic, and lumbar spine in whom life expectancy is of insufficient duration to permit achievement of fusion, with bone graft used at the surgeon's discretion.

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Device Description:

The Modulift VBR System is an adjustable vertebral body replacement device that is implanted into the vertebral body space to improve stability of the spine. The system is comprised of spacers and foot plates of various heights and sizes to fit the anatomical needs of a wide variety of patients. The device can be adjusted to the required height after implantation. Once it is adjusted to the desired height the column is mechanically locked in place by means of locking screws (grub screws). Each spacer has an axial hole to allow grafting material to be packed inside the device. Spikes on the end of the foot plates improve the anchoring of the implant to the vertebral body. The foot plates of the device are available in various lordotic and kyphotic angles. Components are manufactured from titanium alloy (Ti6Al4V) per ASTM F-136, and cobalt chrome (CoCr) per ASTM F1537

The purpose of the subject 510(k) is to expand the indications to include use in the cervical spine (C3-C7) of the small VBR devices.

Primary Predicate Device:
NuVasive X-CORE® Mini Cervical Expandable VBR System (K151651).

Additional Predicate Device:
Aesculap Implant Systems (AIS) Modulift VBR System (K110864/K133802/K142150)

Comparison of Technological Characteristics:
The purpose of this 510(k) is to modify the Indications for Use for the subject Modulift Small VBR Implant. A comprehensive clinical literature review and retrospective study have been provided to investigate the risks and benefits associated with VBR use in the cervical spine. No other changes have been made to the system design since its clearance in the Modulift VBR System 510(k) K133802.

Performance Testing:
The Modulift Small VBR Implant and predicate NuVasive X-CORE® Mini Cervical Expandable VBR System are similar in design, material, and indicated use, and are both cleared devices. A comprehensive clinical literature review and retrospective study has been conducted to investigate the risks and benefits associated with using vertebral body replacement devices in the cervical spine. The clinical literature suggests that there is a positive benefit associated with use of VBR in the cervical spine with minimal risk.

Conclusion:
The Modulift VBR System has been modified to expand the indications to permit use in the cervical spine (C3-C7). Based on the indications for use, technological characteristics, mechanical testing, and comparison to the predicate device, the subject Modulift VBR System has been shown to be substantially equivalent to the legally marketed predicate device(s).