January 10, 2019

Stryker Spine
Renee Norby
Regulatory Affairs Specialist
2 Pearl Court
Allendale, New Jersey 07401

Re: K183071
Trade/Device Name: VLIFT®-s Vertebral Body Replacement System
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal Intervertebral Body Fixation Orthosis
Regulatory Class: Class II
Product Code: PLR, MQP
Dated: December 14, 2018
Received: December 17, 2018

Dear Ms. Norby:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; 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 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,

Melissa Hall -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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K183071

Device Name
VLIFT®-s Vertebral Body Replacement System

Indications for Use *(Describe)*

VLIFT®-s Vertebral Body Replacement System is indicated for use in the cervical spine (C3-C7) and the thoracolumbar spine (T1-L5) 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 tissue in degenerative disorders.

The VLIFT®-s Vertebral Body Replacement 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 VLIFT®-s Vertebral Body Replacement 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 VLIFT®-s Vertebral Body Replacement System is intended to be used with FDA-cleared supplemental spinal fixation systems that have been labeled for use in the cervical, thoracic, and/or lumbar spine (i.e., posterior screw and rod systems, anterior plate systems, and anterior screw and rod systems). When used at more than two levels, supplemental fixation should include posterior fixation.

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

510(k) Summary: VLIFT®-s Vertebral Body Replacement System	
Submitter:	Stryker Spine 2 Pearl Court Allendale, NJ 07401
Contact Person :	Name: Renee Norby Phone: 201-749-8074 Email: renee.norby@stryker.com
Date Prepared:	January 7, 2019
Trade Name:	VLIFT®-s Vertebral Body Replacement System
Common Name:	Spinal Vertebral Body Replacement Device
Proposed Class:	Class II
Classification Name:	Spinal Intervertebral Body Fixation Orthosis (21 CFR 888.3060)
Product Code:	PLR, MQP
Predicate Devices:	The VLIFT®-s Vertebral Body Replacement System was shown to be substantially equivalent to the device listed below: Primary Predicate: • Aesculap® Implant Systems, Inc., Modulift Vertebral Body Replacement (VBR) System, K172032 Additional Predicates: • Zavation Normandy VBR System, K180673 • Globus Medical Inc., FORTIFY® Corpectomy Spacers, K162315 • Cardinal Spine, LLC, C-VBR, K152568 • NuVasive® Incorporated, NuVasive® X-Core® Mini Cervical Expandable VBR System, K151651 • Stryker Spine, VLIFT®-s Vertebral Body Replacement System, K091946 • Ulrich GmbH, Obelisc VBR, K060416 Reference Devices: • Stryker Spine, AVS® AS PEEK Spacer, K120486 • Stryker Spine, Tritanium® C Anterior Cervical Cage, K171496
Device Description:	The VLIFT®-s Vertebral Body Replacement System is intended for use as an aid in spinal fusion and consists of a single, pre-assembled distractible implant. The device may be distracted continuously via an inner concentric ring. The hollow core of the cage allows for packing bone graft. As the implant is distracted via its inner concentric ring, additional slotted openings appear.

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510(k) Summary: VLIFT®-s Vertebral Body Replacement System	
	The VLIFT®-s cages are available in various diameters and heights. Modular end caps snap into each end of the VLIFT®-s implant. Serrated teeth at the rim of the end cap attachments help to anchor the implant to the end plates of the vertebral bodies. The VLIFT®-s end caps are available in both flush and contoured designs and are offered in a variety of angles. Extension pieces are available for each diameter for the VLIFT®-s implants. Extension pieces may be used to achieve the desired height. The use of extension pieces is optional.
Intended Use:	The Stryker Spine VLIFT®-s Vertebral Body Replacement System is indicated for use in the cervical spine (C3-C7) and the thoracolumbar spine (T1-L5) 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 tissue in degenerative disorders. The VLIFT®-s Vertebral Body Replacement 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 VLIFT®-s Vertebral Body Replacement 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 VLIFT®-s Vertebral Body Replacement System is intended to be used with FDA-cleared supplemental spinal fixation systems that have been labeled for use in the cervical, thoracic, and/or lumbar spine (i.e., posterior screw and rod systems, anterior plate systems, and anterior screw and rod systems). When used at more than two levels, supplemental fixation should include posterior fixation.
Summary of the Technological Characteristics	The subject VLIFT®-s Vertebral Body Replacement System and the predicate was shown to be substantially equivalent based on material, design, and mechanical performance. The purpose of this 510(k) submission is to seek clearance for use in the cervical spine. No changes have been made to the actual implants.

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510(k) Summary: VLIFT®-s Vertebral Body Replacement System	
Summary of the Performance Data	The published clinical literature demonstrates the substantial equivalence of VLIFT®-s Vertebral Body Replacement to other legally marketed cervical vertebral body replacement devices. No changes were made to the existing devices, nor were any new components added to the system. Therefore, no additional testing was required or performed.
Conclusion	The design features, materials used, manufacturing, and sterilization methods are identical to the previously cleared VLIFT®-s Vertebral Body Replacement System with the exception of broadening the indications to include the cervical spine. Additionally, the design features, materials used, manufacturing, and sterilization methods are similar to the predicates identified in this submission. Based on information provided, the subject device has been determined to be substantially equivalent to the predicate devices.