SeaSpine Orthopedics Corporation
Gina Flores
Specialist, Regulatory Affairs
5770 Armada Drive
Carlsbad, California 92008

December 21, 2017

Re: K172926
Trade/Device Name: SeaSpine Vu cPOD, Zuma-C, Complete Cervical
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: ODP, OVE
Dated: September 22, 2017
Received: September 25, 2017

Dear Gina Flores:

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,

Katherine D. Kavlock -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)*

K172926

Device Name
SeaSpine Vu c•POD

Indications for Use *(Describe)*

The Vu c•POD Intervertebral Body Fusion Device is indicated for anterior cervical interbody fusion procedures in skeletally mature patients with cervical degenerative disc disease (DDD) at one level from C2-C3 to C7-T1. Cervical degenerative disc disease is defined as neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies.

The Vu c•POD implants are to be used with autograft bone graft and/or allogeneic bone graft composed of cancellous and/or corticocancellous bone and implanted via an open, anterior approach. The cervical device is to be used in patients who have had six weeks of non-operative treatment. The Vu c•POD Intervertebral Body Fusion Device is intended for use with supplemental internal fixation systems.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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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)*

K172926

Device Name
SeaSpine Zuma-C

Indications for Use *(Describe)*

Zuma-C is a stand-alone anterior cervical interbody fusion device intended for use as an adjunct to fusion at one level (C3-C7) in skeletally mature patients with degenerative disc disease (defined as discogenic neck pain with degeneration of the disc confirmed by history and radiographic studies). Patients should have received at least six weeks of non-operative treatment prior to treatment with the device. Zuma-C is to be used with autograft bone graft and/or allogeneic bone graft composed of cancellous and/or corticocancellous bone and implanted via an open, anterior approach. Zuma-C is intended to be used with the bone screw fixation provided and requires no additional 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)

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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)*

K172926

Device Name
SeaSpine Complete Cervical

Indications for Use *(Describe)*

The Complete Cervical Intervertebral Body Fusion Device is indicated for anterior cervical interbody fusion procedures in skeletally mature patients with cervical disc disease at one level from the C2-C3 disc to the C7-T1 disc. Cervical disc disease is defined as neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies.

The Complete Cervical implants are to be used with autograft bone graft and/or allogeneic bone graft composed of cancellous and/or corticocancellous bone and implanted via an anterior approach. The cervical device is to be used in patients who have had six (6) weeks of non-operative treatment. The cervical device is to be used with two 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.

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510(k) Summary

Contact Details

Applicant Name: SeaSpine Orthopedics Corporation

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Contact person: Gina Flores, Sr. Regulatory Specialist
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Date Prepared: September 22, 2017

Device Name

Trade Name: SeaSpine Vu c·POD, Complete Cervical, and Zuma-C

Common Name: Intervertebral Fusion device with bone graft, cervical

Classification Name: Intervertebral fusion device with integrated fixation, cervical (21 CFR 888.3080)

Class: II

Product Code: ODP, OVE

Legally Marketed Predicate Devices

510(k) Number	Product Code	Trade Name	Manufacturer
PRIMARY PREDICATE Device			
K171046	ODP	Cambria System	SeaSpine Orthopedics Corporation
Additional PREDICATE Devices			
K111675,K101363, K050058, K032064	ODP	Vu c·POD	SeaSpine Orthopedics Corporation (originally manufactured by Integra LifeSciences, now SeaSpine Orthopedics Corporation)
K102323	ODP	Complete Cervical	SeaSpine Orthopedics Corporation (originally manufactured by Theken, LLC, now SeaSpine Orthopedics Corporation)
K092521	ODP	Zuma-C	SeaSpine Orthopedics Corporation

Device Description

The SeaSpine Vu c·POD, Complete Cervical, and Zuma-C Systems are intervertebral fusion devices intended to act as a disc spacer and hold bone graft to promote fusion in the cervical spine. All three system spacers are manufactured from PEEK (ASTM F2026), with tantalum (ASTM F560) radiographic markers. The Complete Cervical spacers also include titanium alloy and screws (ASTM F136), while Zuma-C includes titanium screws, as well as plates and set screws (ASTM F136).

Each system spacer is generally box-shaped with a central canal for receiving autograft bone graft material and/or allogeneic bone graft composed of cancellous and/or corticocancellous bone. The systems are implanted via an anterior approach.

The instruments included with each system facilitate the placement and adjustment of the interbody spacers, and removal if necessary. The instruments are placed in trays and caddies for storage, protection, and organization prior to and during the steam sterilization process.

Intended Use/Indications for use

Vu c·POD:

The Vu c•POD Intervertebral Body Fusion Device is indicated for anterior cervical interbody fusion procedures in skeletally mature patients with cervical degenerative disc disease (DDD) at one level from C2-C3 to C7-T1. Cervical degenerative disc disease is defined as neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies.

The Vu c•POD implants are to be used with autograft bone graft and/or allogeneic bone graft composed of cancellous and /or corticocancellous bone and implanted via an open, anterior approach. The cervical device is to be used in patients who have had six weeks of non-operative treatment. The Vu c•POD Intervertebral Body Fusion Device is intended for use with supplemental internal fixation systems.

Complete Cervical:

The Complete Cervical Intervertebral Body Fusion Device is indicated for anterior cervical interbody fusion procedures in skeletally mature patients with cervical disc disease at one level from the C2-C3 disc to the C7-T1 disc. Cervical disc disease is defined as neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies.

The Complete Cervical implants are to be used with autograft bone graft and/or allogeneic bone graft composed of cancellous and /or corticocancellous bone and implanted via an anterior approach. The cervical device is to be used in patients who have had six (6) weeks of non-operative treatment. The cervical device is to be used with two titanium alloy screws which accompany the implant.

Zuma-C:

Zuma-C is a stand-alone anterior cervical interbody fusion device intended for use as an adjunct to fusion at one level (C3-C7) in skeletally mature patients with degenerative disc disease (defined as discogenic neck pain with degeneration of the disc confirmed by

history and radiographic studies). Patients should have received at least six weeks of non-operative treatment prior to treatment with the device. Zuma-C is to be used with autograft bone graft and/or allogeneic bone graft composed of cancellous and /or corticocancellous bone and implanted via an open, anterior approach. Zuma-C is intended to be used with the bone screw fixation provided and requires no additional fixation.

Summary of Technological Characteristics

The SeaSpine Vu c·POD, Complete Cervical, and Zuma-C Systems and the predicate devices have the same operational principle; they act as a disc spacer and hold bone graft to promote fusion in the cervical spine. The SeaSpine Vu c·POD, Complete Cervical, and Zuma-C Systems are substantially equivalent to the cited predicate devices in areas including intended use/indications for use, technological characteristics (operating principle, design, materials, sterility, manufacturing, etc.) and performance (mechanical safety).

Non-Clinical Testing

There are no changes to the design, materials, specifications or manufacture of the implants, therefore no mechanical testing was performed for the Vu c Pod and Complete Cervical systems.

Engineering analysis verified that the device modifications in the Zuma-C did not create any new worst cases with respect to mechanical performance. Conclusions from previously performed mechancial testing per ASTM F2077 and F2267 remain valid.

Clinical Testing

Not applicable; determination of substantial equivalence is not based on an assessment of clinical performance data.

Conclusions

The submitted data demonstrate that the SeaSpine Vu c·POD, Complete Cervical, and Zuma-C Systems are substantially equivalent to the cited legally marketed predicate devices