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

July 7, 2017

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

Re: K171046
Trade/Device Name: SeaSpine Cambria System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: ODP
Dated: April 6, 2017
Received: April 7, 2017

Dear Ms. 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.

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,

Vincent J. Devlin -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)*
K171046

Device Name
SeaSpine Cambria NanoMetalene System

Indications for Use *(Describe)*
Cambria NanoMetalene is intended to be used as an adjunct to spinal fusion procedures at one or two contiguous levels (C3-C7) in skeletally mature patients with degenerative disc disease (defined as neck pain with discogenic origin with degeneration of the disc confirmed by history and radiographic studies) of the cervical spine. Patients should have received at least six weeks of non-operative treatment prior to treatment with the device. Devices are intended to be implanted via an open, anterior approach and used with autograft bone graft and/or allogeneic bone graft composed of cancellous and /or corticocancellous bone and supplemental fixation, such as an anterior plating 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.

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

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

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Food and Drug Administration
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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)*
K171046

Device Name
SeaSpine Cambria System

Indications for Use *(Describe)*
Cambria is intended to be used as an adjunct to spinal fusion procedures at one or two contiguous levels (C3-C7) in skeletally mature patients with degenerative disc disease (defined as neck pain with discogenic origin with degeneration of the disc confirmed by history and radiographic studies) of the cervical spine. Patients should have received at least six weeks of non-operative treatment prior to treatment with the device. Devices are intended to be implanted via an open, anterior approach and used with autograft bone graft and/or allogeneic bone graft composed of cancellous and /or corticocancellous bone and supplemental fixation, such as an anterior plating 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)

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510(k) Summary

Contact Details

Applicant Name: SeaSpine Orthopedics Corporation

Address: 5770 Armada Drive, Carlsbad CA
Phone number: (760) 216-5136
Fax number: (760) 683-6874

Contact person: Gina Flores, Sr. Regulatory Specialist
Email address: gina.flores@seaspine.com

Date Prepared: July 5, 2017

Device Name

Trade Name: SeaSpine Cambria System

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

Legally Marketed Predicate Devices

510(k) Number	Product Code	Trade Name	Manufacturer
PRIMARY PREDICATE Device			
K082309	ODP	Cambria System	SeaSpine Orthopedics Corporation
Additional PREDICATE Devices			
K162715	ODP	Cambria NanoMetalene Sterile	SeaSpine Orthopedics Corporation
K142488	ODP	Cambria NanoMetalene	SeaSpine Orthopedics Corporation
K151322	MAX, ODP	Zeus-C-Amendia Interbody Fusion Device	Amendia, Inc.

Device Description

The Cambria System device is an intervertebral fusion device intended to act as a disc spacer and hold bone graft to promote fusion in the cervical spine. The cervical spacers are manufactured from PEEK (ASTM F2026), with tantalum (ASTM F560) radiographic markers, and are 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 system is implanted via an anterior approach.

The Cambria System device is offered in a variety of heights and footprints to accommodate variations in patient anatomy. The cervical spacers are offered in all PEEK or with a surface coating of commercially pure titanium (ASTM F67) referred to as NanoMetalene (NM).

The Cambria NanoMetalene cervical spacers are provided in gamma sterilized packaging; the Cambria PEEK implants are provided non-sterile for subsequent sterilization at the healthcare facility.

The instruments included with the Cambria System facilitate the placement and adjustment of the interbody spacers, and removal if necessary. The instruments also include the trays and caddies for storage, protection, and organization prior to and during the steam sterilization process.

Intended Use/Indications for use

Cambria

Cambria is intended to be used as an adjunct to spinal fusion procedures at one or two contiguous levels (C3-C7) in skeletally mature patients with degenerative disc disease (defined as neck pain with discogenic origin with degeneration of the disc confirmed by history and radiographic studies) of the cervical spine. Patients should have received at least six weeks of non-operative treatment prior to treatment with the device. Devices are intended to be implanted via an open, anterior approach and used with autograft bone graft and/or allogeneic bone graft composed of cancellous and /or corticocancellous bone and supplemental fixation, such as an anterior plating system.

Cambria NanoMetalene

Cambria NanoMetalene is intended to be used as an adjunct to spinal fusion procedures at one or two contiguous levels (C3-C7) in skeletally mature patients with degenerative disc disease (defined as neck pain with discogenic origin with degeneration of the disc confirmed by history and radiographic studies) of the cervical spine. Patients should have received at least six weeks of non-operative treatment prior to treatment with the device. Devices are intended to be implanted via an open, anterior approach and used with autograft bone graft and/or allogeneic bone graft composed of cancellous and /or corticocancellous bone and supplemental fixation, such as an anterior plating system.

Summary of Technological Characteristics

The Cambria System and predicate devices have the same operating principle; they act as a disc spacer and hold bone graft to promote fusion in the cervical spine. The Cambria System is 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).

The subject and predicate devices are based on the following similar technological elements:

- Spacer Heights
- Spacer Footprints
- Spacer Lordotic Angle
- Implant Materials

Non-Clinical Testing

Engineering analysis verified that the device modifications did not create any new worst cases with respect to mechanical performance; conclusions from the previously performed axial compression, compression shear, and torsion testing (ASTM F2077), subsidence testing (ASTM F2267), and expulsion testing (lab protocol) remained valid.

For the Cambria NanoMetalene System implants, packaging, shipping and sterilization tests were performed to validate a Sterility Assurance Level (SAL) of 10^{-6} and ensure maintenance of a sterile barrier. Bacterial Endotoxin testing (BET) was conducted in accordance with ANSI/AAMI ST-72:2011.

Clinical Testing

An assessment of clinical literature data was completed to support the proposed indication for use of the Cambria System at 2 contiguous levels (C3-C7).

Conclusions

The submitted data demonstrate that the SeaSpine Cambria System are substantially equivalent to the cited legally marketed predicate. The clinical data demonstrate that the Cambria System device performs comparably to the predicate device that is currently marketed for the same intended use.