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

October 28, 2016

SeaSpine® Orthopedics Corporation
% Ms. Gina Flores
Regulatory Specialist
5770 Armada Drive
Carlsbad, California 92008

Re: K162715
Trade/Device Name: SeaSpine® Spacer System - Hollywood NanoMetalene®, Hollywood VI NanoMetalene®, Ventura NanoMetalene®; SeaSpine® Cambria NanoMetalene®
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: MAX, ODP
Dated: September 28, 2016
Received: September 29, 2016

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,

Mark N. Melkerson -S

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)*
K162715

Device Name
SeaSpine® Spacer System - Hollywood NanoMetalene® , Hollywood VI NanoMetalene®, and Ventura NanoMetalene®

Indications for Use *(Describe)*

SeaSpine® Spacer System – Hollywood NanoMetalene®, Hollywood VI NanoMetalene®, and Ventura NanoMetalene®:

When used as an intervertebral body fusion device, the system is intended for spinal fusion procedures at one or two contiguous levels (L2-S1) in skeletally mature patients with degenerative disc disease (DDD). DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. DDD patients may also have up to Grade 1 spondylolisthesis or retrolisthesis at the involved level(s). These patients may have had a previous non-fusion spinal surgery at the involved spinal level(s). These patients should have had six months of non-operative treatment. The device is intended to be used with autogenous bone graft (autograft) and supplemental 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.

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)*
K162715

Device Name
SeaSpine® Cambria NanoMetalene®

Indications for Use *(Describe)*

Cambria is intended to be used as an adjunct to spinal fusion procedures at one level (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 autogenous 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.

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K162715
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, Regulatory Specialist
Email address: gina.flores@SeaSpine.com

Date Prepared: October 27, 2016

Device Name

Trade Name: SeaSpine® Spacer System - Hollywood NanoMetalene®, Hollywood VI NanoMetalene®, Ventura NanoMetalene®
SeaSpine® Cambria NanoMetalene®

Common Name: Intervertebral Body Fusion Device

Classification Name: Intervertebral body fusion device

(21 CFR 888.3080)

Class: II

Product Code: MAX, ODP

Legally Marketed Predicate Devices

510(k) Number	Product Code	Trade Name	Manufacturer
Primary Predicate Device			
K102026	MAX, MQP	SeaSpine® Spacer System- (Hollywood NanoMetalene®)	SeaSpine® Orthopedics Corporation
Predicate Device			
K142488	MAX, ODP	SeaSpine® Spacer System (Hollywood VI NanoMetalene®, Ventura NanoMetalene®) and Cambria NanoMetalene®	SeaSpine® Orthopedics Corporation

Device Description

The SeaSpine® Spacer System (Hollywood NanoMetalene®, Hollywood VI NanoMetalene®, Ventura NanoMetalene®), and the Cambria NanoMetalene® are intervertebral fusion devices manufactured from polyetheretherketone (PEEK OPTIMA LT1 per ASTM F2026) with markers (tantalum per ASTM F560 or Ti-6Al-4V ELI per ASTM F136) for radiographic visualization. The implants have a one-micron thick surface coat of commercially pure (CP) titanium. The devices have a central canal for receiving autogenous bone graft and are offered in a variety of sizes and geometries to accommodate variations in pathology and patient anatomy. The purpose of this 510(k) is to receive clearance to offer the interbody devices of the noted systems gamma sterilized in individual packaging.

Intended Use/Indications for use

The NanoMetalene® subject devices have substantially equivalent indications and intended use as the cited predicates:

SeaSpine® Spacer System (Hollywood NanoMetalene®, Hollywood VI NanoMetalene®, Ventura NanoMetalene®):

When used as an intervertebral body fusion device, the system is intended for spinal fusion procedures at one or two contiguous levels (L2-S1) in skeletally mature patients with degenerative disc disease (DDD). DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. DDD patients may also have up to Grade 1 spondylolisthesis or retrolisthesis at the involved level(s). These patients may have had a previous non-fusion spinal surgery at the involved spinal level(s). These patients should have had six months of non-operative treatment. The device is intended to be used with autogenous bone graft (autograft) and supplemental fixation.

Cambria NanoMetalene®:

Cambria is intended to be used as an adjunct to spinal fusion procedures at one level (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 autogenous bone and supplemental fixation, such as an anterior plating system.

Summary of Technological Characteristics

The SeaSpine® Spacer System (Hollywood NanoMetalene®, Hollywood VI NanoMetalene®, Ventura NanoMetalene®), and the Cambria NanoMetalene® devices 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).

	Subject Devices: Hollywood NanoMetalene® System Hollywood VI NanoMetalene® System Ventura NanoMetalene® System Cambria NanoMetalene® System	**Predicate Devices:** Hollywood NanoMetalene® System Hollywood VI NanoMetalene® System Ventura NanoMetalene® System Cambria NanoMetalene® System
Intended Use	Adjunct to spinal fusion procedures in skeletally mature patients with degenerative disc disease (DDD)	Adjunct to spinal fusion procedures in skeletally mature patients with degenerative disc disease (DDD)
Materials	PEEK-OPTIMA (ASTM 2026), Titanium alloy (ASTM F136), Tantalum, (ASTM F560), CP Titanium Surface (ASTM F67)	PEEK-OPTIMA (ASTM 2026), Titanium alloy (ASTM F136), Tantalum, (ASTM F560), CP Titanium Surface (ASTM F67)
Design	Varying footprints and heights with a central channel to be filled with autogenous bone graft to allow for bone fusion.	Varying footprints and heights with a central channel to be filled with autogenous bone graft to allow for bone fusion.
Performance Testing	No new testing required	Analysis and static & dynamic testing (ASTM F2027), Wear Evaluation (ASTM F1877), Subsidence (ASTM F2267)
Packaging	Implants will be double packaged in PETG trays with Tyvek lids. Components, accessories and instruments are provided trays/caddies intended for sterilization by the end user	N/A – System implants, components, accessories and instruments are provided in trays/caddies intended for sterilization by the end user
Sterilization	Implants will be provided in sterile packaging validated to ensure a SAL 10^{-6} Components, accessories and instruments are sterilized by the end user	System implants, components, accessories and instruments are sterilized by the end user

Non-Clinical Testing

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

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

Conclusions

The submitted data demonstrate that the SeaSpine® Spacer System (Hollywood NanoMetalene®, Hollywood VI NanoMetalene®, Ventura NanoMetalene®), and Cambria NanoMetalene® devices are as safe, as effective, and perform at least as safely and effectively as the cited legally marketed predicates.