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

December 4, 2017

Re: K173260
Trade/Device Name: SeaSpine Spacer System (NanoMetalene)- Hollywood, Hollywood VI, Ventura, Pacifica; SeaSpine Spacer System -Hollywood, Hollywood VI, Ventura, Pacifica; SeaSpine Vu e·POD System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: MAX, MQP
Dated: October 9, 2017
Received: October 10, 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 (DICE) 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 (DICE) 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,

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)*
K173260

Device Name
SeaSpine Spacer System (NanoMetalene)-Hollywood, Hollywood VI, Ventura, Pacifica

Indications for Use *(Describe)*
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 autograft bone graft and/or allogeneic bone graft composed of cancellous and/or corticocancellous bone 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.

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

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Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
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Indications for Use

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Device Name
SeaSpine Spacer System- Hollywood, Hollywood VI, Ventura, Pacifica

Indications for Use *(Describe)*
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 autograft bone graft and/or allogeneic bone graft composed of cancellous and/or corticocancellous bone and supplemental fixation.

When used as a vertebral body replacement device (VBR) the SeaSpine Spacer System is intended for use in the thoracolumbar spine (T1 to L5) to replace a collapsed, diseased, damaged or unstable complete or partial vertebral body due to tumor or trauma/fracture, to achieve anterior decompression of the spinal cord and neural tissues, and to restore the height of a collapsed vertebral body. The SeaSpine Spacer System is designed to restore the biomechanical integrity of the anterior, middle, and posterior spinal column, even in the absence of fusion for a prolonged period. Additionally, the SeaSpine Spacer System is intended for use with autograft bone graft and/or allogeneic bone graft composed of cancellous and/or corticocancellous bone.

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)*
K173260

Device Name
SeaSpine Vu e•POD System

Indications for Use *(Describe)*
When used as an intervertebral body fusion device, the Vu e•POD Intervertebral Body Fusion Device is indicated for use as an adjunct to fusion in patients with degenerative disc disease (DDD) at one or two contiguous levels from L2 to S1. These DDD patients may also have up to Grade 1 spondylolisthesis at the involved level(s). The device is indicated for use with autograft bone graft and/or allogeneic bone graft composed of cancellous and/or corticocancellous bone. The Vu e•POD Intervertebral Body Fusion Devices are intended for use with supplemental fixation.
Degenerative disc disease (DDD) is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. These patients should be skeletally mature and have had six months of non-operative treatment.

When used as a vertebral body replacement (VBR) the Vu e•POD System is indicated for use in the thoracolumbar spine (TI-L5) to replace a collapsed, damaged or otherwise unstable vertebral body due to tumor or trauma (i.e. fracture). The Vu e•POD VBR System is designed to restore the biomechanical integrity of the anterior, middle and posterior spinal column even in the absence of fusion for a prolonged period. The device is indicated for use with autograft bone graft and/or allogeneic bone graft composed of cancellous and/or corticocancellous bone. The Vu e•POD VBR System is intended for use with supplemental internal spinal 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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510(k) Summary **K173260**

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: October 24, 2017

Device Name

	Trade Name	Common Name	Classification Name	Class	Product Code
1	SeaSpine Spacer System (NanoMetalene)-Hollywood, Hollywood VI, Ventura, Pacifica	Intervertebral Fusion Device with Bone Graft, Lumbar	Intervertebral Body Fusion Device (21 CFR 888.3080)	Class II	MAX
2	SeaSpine Spacer System - Hollywood, Hollywood VI, Ventura, Pacifica	Intervertebral Fusion Device with Bone Graft, Lumbar	Intervertebral Body Fusion Device (21 CFR 888.3080)	Class II	MAX
		Spinal Vertebral Body Replacement Device	Spinal Intervertebral Body Fixation Orthosis (21 CFR 888.3060)		MQP
3	SeaSpine Vu e·POD System	Intervertebral Fusion Device with Bone Graft, Lumbar	Intervertebral Body Fusion Device (21 CFR 888.3080)	Class II	MAX
		Spinal Vertebral Body Replacement Device	Spinal Intervertebral Body Fixation Orthosis (21 CFR 888.3060)		MQP

Legally Marketed Predicate Devices

1. SeaSpine Spacer System (NanoMetalene)-Hollywood, Hollywood VI, Ventura, Pacifica:

510(k) Number	Product Code	Trade Name	Manufacturer
PRIMARY PREDICATE Device			
K162715, K142488, K102026	MAX	SeaSpine Spacer System Hollywood, Hollywood VI, Ventura	SeaSpine Orthopedics Corporation
Additional PREDICATE Devices			
K162351	OVD	Vu a•POD Prime NanoMetalene	SeaSpine Orthopedics Corporation

2. SeaSpine Spacer System-Hollywood, Hollywood VI, Ventura, Pacifica:

510(k) Number	Product Code	Trade Name	Manufacturer
PRIMARY PREDICATE Device			
K082310	MQP, MAX	SeaSpine Spacer System: Hollywood, Hollywood VI, Ventura, Pacifica	SeaSpine Orthopedics Corporation
Additional PREDICATE Devices			
K162351	OVD	Vu a•POD Prime NanoMetalene	SeaSpine Orthopedics Corporation

3. SeaSpine Vu e·POD System:

510(k) Number	Product Code	Trade Name	Manufacturer
PRIMARY PREDICATE Device			
K082712	MQP, MAX	SeaSpine Vu e·POD System (PEEK)	SeaSpine Orthopedics Corporation (originally manufactured by Theken, LLC)
Additional PREDICATE Devices			
K162351	OVD	Vu a•POD Prime NanoMetalene	SeaSpine Orthopedics Corporation

Device Description

The SeaSpine Spacer System (Hollywood, Hollywood VI, Ventura, Pacifica), and Vu e·POD, are intervertebral fusion devices intended to promote spinal fusion by acting as a disc spacer and holding autograft bone graft and/or allogeneic bone graft composed of cancellous and /or corticocancellous bone. The implants have teeth on the superior and inferior surfaces and a central canal for receiving the autograft. The devices are available in a variety of shapes, lengths, widths, and heights to accommodate variations in pathology and patient anatomy. All implants are manufactured from PEEK (per ASTM F2026) with radiographic markers manufactured from tantalum (per ASTM F560). The implants are offered either in all PEEK (ASTM F2026) or coated with commercially pure titanium (ASTM F67), NanoMetalene.

The NanoMetalene spacers are provided in gamma sterilized packaging, while the PEEK spacers are provided non-sterile for subsequent sterilization at the healthcare facility.

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

SeaSpine Spacer System (NanoMetalene)- Hollywood, Hollywood VI, Ventura, Pacifica

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 *autograft bone graft and/or allogeneic bone graft composed of cancellous and/or corticocancellous bone* and supplemental fixation.

SeaSpine Spacer System- Hollywood, Hollywood VI, Ventura, Pacifica

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 *autograft bone graft and/or allogeneic bone graft composed of cancellous and/or corticocancellous bone* and supplemental fixation.

When used as a vertebral body replacement device (VBR) the SeaSpine Spacer System is intended for use in the thoracolumbar spine (T1 to L5) to replace a collapsed, diseased, damaged or unstable complete or partial vertebral body due to tumor or trauma/fracture, to achieve anterior decompression of the spinal cord and neural tissues, and to restore the height of a collapsed vertebral body. The SeaSpine Spacer System is designed to restore the biomechanical integrity of the anterior, middle, and posterior spinal column, even in the absence of fusion for a prolonged

period. Additionally, the SeaSpine Spacer System is intended for use with autograft bone graft and/or allogeneic bone graft composed of cancellous and/or corticocancellous bone.

SeaSpine Vu e·POD System

When used as an intervertebral body fusion device, the Vu e•POD Intervertebral Body Fusion Device is indicated for use as an adjunct to fusion in patients with degenerative disc disease (DDD) at one or two contiguous levels from L2 to S1. These DDD patients may also have up to Grade 1 spondylolisthesis at the involved level(s). The device is indicated for use with *autograft bone graft and/or allogeneic bone graft composed of cancellous and/or corticocancellous bone*. The Vu e•POD Intervertebral Body Fusion Devices are intended for use with supplemental fixation.

Degenerative disc disease (DDD) is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. These patients should be skeletally mature and have had six months of non-operative treatment.

When used as a vertebral body replacement (VBR) the Vu e•POD System is indicated for use in the thoracolumbar spine (TI-L5) to replace a collapsed, damaged or otherwise unstable vertebral body due to tumor or trauma (i.e. fracture). The Vu e•POD VBR System is designed to restore the biomechanical integrity of the anterior, middle and posterior spinal column even in the absence of fusion for a prolonged period. The device is indicated for use with *autograft bone graft and/or allogeneic bone graft composed of cancellous and/or corticocancellous bone*. The Vu e•POD VBR System is intended for use with supplemental internal spinal fixation.

Summary of Technological Characteristics

The SeaSpine Spacer System (Hollywood, Hollywood VI, Ventura, and Pacifica), and Vu e·POD System and the predicate devices have the same operational principle; they act as a disc spacer and hold bone graft to promote fusion in the spine. The SeaSpine Spacer System, and Vu e·POD 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.

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, Hollywood VI, Ventura, Pacifica), and Vu e·POD Systems are substantially equivalent to the cited legally marketed predicate devices.