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

December 1, 2016

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

Re: K162351
Trade/Device Name: SeaSpine® Vu a•POD™ Prime NanoMetalene® Intervertebral Body Fusion Device
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: OVD
Dated: November 22, 2016
Received: November 23, 2016

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.

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

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K162351

Device Name
SeaSpine® Vu a•POD™ Prime NanoMetalene® Intervertebral Body Fusion Device

Indications for Use *(Describe)*

When used with the bone screws, the SeaSpine® Vu a•POD™ Prime NanoMetalene® Intervertebral Body Fusion Device is indicated for use as an adjunct to fusion in skeletally mature patients with degenerative disc disease (DDD) at one or two contiguous levels from L2 to S1. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The DDD patients may also have up to Grade 1 spondylolisthesis at the involved level(s).The interior of the interbody spacer component may be packed with autogenous bone graft and/or allogeneic bone graft material composed of cancellous and/or corticocancellous bone.

When used with the SpinPlate™, the Vu a•POD™ Prime NanoMetalene® Intervertebral Body Fusion Device is indicated for use as an adjunct to fusion in skeletally mature patients with degenerative disc disease (DDD) at one or two contiguous levels from L2 to S1. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. These DDD patients may also have up to Grade 1 spondylolisthesis at the involved level(s).The interior of the interbody spacer component may be packed with autogenous bone graft and/or allogeneic bone graft material composed of cancellous and/or corticocancellous bone. When used with the SpinPlate™, the Vu a•POD™ Prime NanoMetalene® Intervertebral Body Fusion Device is intended for use with supplemental fixation.

The Vu a•POD™ Prime NanoMetalene® Intervertebral Body Fusion Device, when used with bone screws or bone screws and the SpinPlate™, is a stand-alone device. If the Vu a•POD™ Prime NanoMetalene® Intervertebral Body Fusion Device is used only with the SpinPlate™ ,then additional supplemental fixation, which has been cleared by the FDA for use in the lumbar spine, must be used to augment stability. Additionally, implants with hyperlordotic angles of >20º must also be used with additional supplemental fixation (e.g. posterior pedicle screw and rod systems). This device is intended to be used with autogenous bone graft and/or allogeneic bone graft material composed of cancellous and/or corticocancellous bone.

Patients must have undergone a regimen of at least six (6) months of non-operative treatment prior to being treated with the device.

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 **K162351**

Contact Details

Applicant Name: SeaSpine® Orthopedics Corporation

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

Date Prepared: November 30, 2016

Device Name

Trade Name: SeaSpine® Vu a•POD™ Prime NanoMetalene® Intervertebral Body Fusion Device

Common Name: Intervertebral Body Fusion Device

Classification Name: Intervertebral body fusion device (21 CFR 888.3080)

Class: II

Product Code: OVD

Legally Marketed Predicate Devices

510(k) Number	Product Code	Trade Name	Manufacturer
PRIMARY PREDICATE Device			
K121211	OVD	Vu a•POD™ Intervertebral Body Fusion Device	SeaSpine® Orthopedics Corp.
Predicate Devices			
K142488	MAX	Vu a•POD-L™ Intervertebral Body Fusion Device NanoMetalene®	SeaSpine® Orthopedics Corp.
K161379	OVD, MAX	ELSA™ Spacers	Globus Medical, Inc.

Device Description

The SeaSpine® Vu a•POD™ Prime NanoMetalene® is an anterior intervertebral body fusion device (IBD) which can be used in combination with two titanium Bone Screws, a titanium SpinPlate™, or both Bone Screws and SpinPlate™ together. When used with Bone Screws or Bone Screws and SpinPlate™, the system is a stand-alone device. When used with the SpinPlate™ alone, the system is intended for use with supplemental fixation. The spacer is intended to be used at one or two contiguous levels from L2 to S1 in the ALIF approach. Implants with hyperlordotic angles of >20° must also be used with additional supplemental fixation (e.g. posterior pedicle screw and rod systems).

The Vu a•POD™ Prime NanoMetalene® IBD spacers are comprised of PEEK-OPTIMA® LT1 polymer and include large central graft windows, which are packed with autogenous bone graft and/or allogeneic bone graft, composed of cancellous and/or corticocancellous bone prior to implantation. The spacers include toothed spikes/knurls on the top and bottom surfaces to engage with the superior and inferior end plates of neighboring vertebral bodies to resist rotation and migration. The spacers have a one-micrometer thick layer of commercially pure (CP) titanium, NanoMetalene® (NM), that is molecularly bonded to the surface. Tantalum pins (i.e. radiopaque markers) are press fit into each end of the radiolucent spacer to allow easier radiological assessment of the position and orientation. The spacer will be provided in sterile packaging; the Bone Screws and SpinPlate™ will be provided non-sterile for subsequent sterilization at the healthcare facility.

The instruments included with the Vu a•POD™ Prime NanoMetalene® IBD system facilitate the placement, adjustment, and final locking 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

When used with the Bone Screws, the SeaSpine® Vu a•POD™ Prime NanoMetalene® Intervertebral Body Fusion Device is indicated for use as an adjunct to fusion in skeletally mature patients with degenerative disc disease (DDD) at one or two contiguous levels from L2 to S1. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The DDD patients may also have up to Grade 1 spondylolisthesis at the involved level(s).The interior of the interbody spacer component may be packed with autogenous bone graft and/or allogeneic bone graft material composed of cancellous and/or corticocancellous bone.

When used with the SpinPlate™, the Vu a•POD™ Prime NanoMetalene® Intervertebral Body Fusion Device is indicated for use as an adjunct to fusion in skeletally mature patients with degenerative disc disease (DDD) at one or two contiguous levels from L2 to S1. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. These DDD patients may also have up to Grade 1 spondylolisthesis at the involved level(s).The interior of the interbody spacer component may be packed with autogenous bone graft and/or allogeneic bone graft material composed of cancellous and/or

corticocancellous bone. When used with the SpinPlate™, the Vu a•POD™ Prime NanoMetalene® Intervertebral Body Fusion Device is intended for use with supplemental fixation.

The Vu a•POD™ Prime NanoMetalene® Intervertebral Body Fusion Device, when used with Bone Screws or Bone Screws and the SpinPlate™, is a stand-alone device. If the Vu a•POD™ Prime NanoMetalene® Intervertebral Body Fusion Device is used only with the SpinPlate™ then additional supplemental fixation, which has been cleared by the FDA for use in the lumbar spine, must be used to augment stability. Additionally, implants with hyperlordotic angles of >20° must also be used with additional supplemental fixation (e.g. posterior pedicle screw and rod systems). This device is intended to be used with autogenous bone graft and/or allogeneic bone graft material composed of cancellous and/or corticocancellous bone.

Patients must have undergone a regimen of at least six (6) months of non-operative treatment prior to being treated with the device.

Technological Characteristics

The SeaSpine® Vu a•POD™ Prime NanoMetalene® IBD 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).

Non-Clinical Testing

The SeaSpine® Vu a•POD™ Prime NanoMetalene® IBD System demonstrated equivalent performance to the predicate through static and dynamic axial compression, compression shear, and torsion testing per ASTM F2077, subsidence testing per ASTM F2267, and expulsion. 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® Vu a•POD™ Prime NanoMetalene® IBD System is as safe, as effective, and performs at least as safely and effectively as the cited legally marketed predicate.