November 25, 2020

SeaSpine Orthopedics Corporation
Ms. Jesse Albright
Specialist, Regulatory Affairs
5770 Armada Drive
Carlsbad, California 92008

Re: K201193
Trade/Device Name: SeaSpine Spacer System NM (Hollywood, Hollywood VI, Pacifica, Redondo, Ventura), Vu aoPOD-L NanoMetalene; SeaSpine Vu eoPOD System; and SeaSpine Reef TH System, SeaSpine Vu aoPOD Prime NanoMetalene IBD; and SeaSpine Shoreline ACS, SeaSpine Cambria System; SeaSpine Regatta Lateral System; and SeaSpine Meridian System, Shoreline Cervical Interbody RT System; and SeaSpine Beachside System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: MAX, ODP, MQP, OVD, OVE
Dated: October 23, 2020
Received: October 27, 2020

Dear Ms. Albright:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Brent L. Showalter, Ph.D.
Assistant Director
DHT6B: Division of Spinal Devices
OHT6: Office of Orthopedic Devices
Office of Product Evaluation and Quality
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K201193

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

Indications for Use *(Describe)*
When used as an intervertebral body fusion device, the SeaSpine Spacer System with NanoMetalene® surface technology 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 and/or allogeneic bone graft composed of cancellous, cortical, 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)

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510(k) Number *(if known)*
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Device Name
SeaSpine Vu a•POD-L NanoMetalene Intervertebral Body Fusion Device

Indications for Use *(Describe)*
The SeaSpine Vu a•POD-L NanoMetalene Intervertebral Body Fusion Device with NanoMetalene® surface technology 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 to be packed with autogenous bone graft and/or allogeneic bone graft composed of cancellous, cortical, and/or corticocancellous bone. The SeaSpine Vu a•POD-L NanoMetalene Intervertebral Body Fusion Device is intended for use with supplemental fixation that is in addition to the integrated buttress spin plate, such as a pedicle screw system or anterior plate. Degenerative disc disease 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 at least six (6) months of non-operative treatment.

Type of Use *(Select one or both, as applicable)*

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Device Name
SeaSpine Vu e•POD System

Indications for Use *(Describe)*
When used as an intervertebral body fusion device, the SeaSpine Vu e•POD System with NanoMetalene® surface technology 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 autogenous bone graft and/or allogeneic bone graft composed of cancellous, cortical, and/or corticocancellous bone. The SeaSpine Vu e•POD System is 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 SeaSpine 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 SeaSpine Vu e•POD 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 autogenous bone graft and/or allogeneic bone graft composed of cancellous, cortical, and/or corticocancellous bone. The SeaSpine Vu e•POD 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) Number *(if known)*
K201193

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 with NanoMetalene® surface technology 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 composed of cancellous, cortical, and/or corticocancellous bone.

When used with the SpinPlate, 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. 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 composed of cancellous, cortical, and/or corticocancellous bone. When used with the SpinPlate, the SeaSpine Vu a•POD Prime NanoMetalene Intervertebral Body Fusion Device is intended for use with supplemental fixation.

The SeaSpine Vu a•POD Prime NanoMetalene Intervertebral Body Fusion Device, when used with the bone screws or the bone screws and the SpinPlate, is a stand-alone device. If the SeaSpine 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 >20̊ 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 composed of cancellous, cortical, 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)

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510(k) Number *(if known)*
K201193

Device Name
Shoreline ACS (Anterior Cervical System)

Indications for Use *(Describe)*
The Shoreline ACS (Anterior Cervical System) with NanoMetalene® surface technology are interbody fusion devices intended for anterior cervical interbody fusion procedures in skeletally mature patients with degenerative disc disease (DDD) of the cervical spine. DDD is defined as discogenic pain with degeneration of the disc confirmed by history and radiographic studies. The Shoreline ACS implants are to be used with autogenous bone graft and/or allogeneic bone graft composed of cancellous, cortical, and/or corticocancellous bone and implanted via an anterior approach. The device is to be used in patients who have had at least six (6) weeks of non-operative treatment.

When used as a standalone system, Shoreline ACS is intended to be used as an adjunct to spinal fusion procedures at one level (C2-T1) and must be used with the Shoreline ACS bone screw fixation and locking cover.

When used with supplemental fixation, such as anterior cervical plates, the Shoreline Cervical low profile (TruProfile) Interbody Spacer is intended to be used as an adjunct to spinal fusion procedures at one or two levels of the cervical spine (C2-T1).

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) Number *(if known)*
K201193

Device Name
SeaSpine Cambria System

Indications for Use *(Describe)*
The SeaSpine Cambria System 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 autogenous bone graft and/or allogeneic bone graft composed of cancellous, cortical, 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) Number *(if known)*
K201193

Device Name
SeaSpine Cambria NanoMetalene System

Indications for Use *(Describe)*
The SeaSpine Cambria NanoMetalene System with NanoMetalene® surface technology 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 autogenous bone graft and/or allogeneic bone graft composed of cancellous, cortical, 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) Number *(if known)*
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Device Name
SeaSpine Regatta Lateral System

Indications for Use *(Describe)*

Interbody Device (IBD) Implants (i.e., interbody implants used alone):
The SeaSpine Regatta Lateral System with NanoMetalene® surface technology is indicated for use as an adjunct to fusion in skeletally mature patients with degenerative disc disease (DDD, defined as back pain of discogenic origin, with degeneration of the disc confirmed by history and radiographic studies). It is intended for use at either one level or two contiguous levels in the lumbar spine, from L2 to S1, for the treatment of DDD with 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 composed of cancellous, cortical, 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.

The SeaSpine Regatta Lateral System is intended for use with supplemental fixation.

TruProfile Interbody Implants:
The SeaSpine Regatta Lateral System assembled with the TruProfile Lateral Plate, when used with Screws, is a standalone interbody implant 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 spacer component may be packed with autogenous bone graft and/or allogeneic bone graft composed of cancellous, cortical, 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.

The SeaSpine Regatta Lateral System assembled with the 1-hole TruProfile Lateral Plate, when used with Screws, is intended for use with 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)

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K201193

Device Name
Shoreline Cervical Interbody RT System

Indications for Use *(Describe)*
The Shoreline Cervical Interbody RT System with NanoMetalene® surface technology are interbody fusion devices intended for use in skeletally mature patients with degenerative disc disease (DDD) of the cervical spine (C2-T1) for one or two contiguous levels, depending on the system. DDD is defined as discogenic pain with degeneration of the disc confirmed by history and radiographic studies. These patients should be skeletally mature and have had at least six (6) weeks of non-operative treatment. These devices are to be filled with autogenous bone graft and/or allogeneic bone graft composed of cancellous, cortical, and/or corticocancellous bone.

When used as a standalone system, the Shoreline Cervical Interbody RT System is intended to be used as an adjunct to spinal fusion procedures at a single level (C2-T1) and must be used with the Shoreline ACS bone screw fixation and locking cover.

When used with supplemental fixation, such as anterior cervical plates, the Shoreline Cervical Interbody RT System is intended to be used as an adjunct to spinal fusion procedures at one or two levels of the cervical spine (C3-C7).

When the system is used at two contiguous levels, the Shoreline Cervical Interbody RT System must be used with 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)

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Device Name
SeaSpine Reef TO/TA System

Indications for Use *(Describe)*
When used as an intervertebral body fusion device, the SeaSpine Reef TO/TA System with NanoMetalene® surface technology 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 and/or allogeneic bone graft composed of cancellous, cortical, 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)

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Device Name
SeaSpine Reef TH System

Indications for Use *(Describe)*
The SeaSpine Reef TH System with NanoMetalene® surface technology 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 and/or allogeneic bone graft composed of cancellous, cortical, 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)

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510(k) Number *(if known)*
K201193

Device Name
SeaSpine Meridian System

Indications for Use *(Describe)*

Interbody Device (IBD) Implants (i.e., interbody implants used alone):
The SeaSpine Meridian System with NanoMetalene® surface technology interbody 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 interior of the device is to be used with autogenous bone graft and/or allogeneic bone graft composed of cancellous, cortical, and/or corticocancellous bone. The SeaSpine Meridian Interbody is intended for use with supplemental fixation. Degenerative disc disease 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 at least six (6) months of non-operative treatment.

No-Profile Implants w/ Screws:
The SeaSpine Meridian System No-Profile Interbody, when used with Screws and a No-Profile Locking Cover, is a standalone interbody implant 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 spacer component may be packed with autogenous bone graft and/or allogeneic bone graft composed of cancellous, cortical, 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. Hyperlordotic sizes (25 and 30 degrees) are intended for use with supplemental fixation.

No-Profile Implants w/ Inline Fixation Anchors:
The SeaSpine Meridian System No-Profile Interbody, when used with Inline Fixation Anchors and a No Profile Locking Cover, 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 spacer component may be packed with autogenous bone graft and/or allogeneic bone graft composed of cancellous, cortical, 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. The SeaSpine Meridian No-Profile Implants w/ Inline Fixation Anchors is intended for use with supplemental fixation.

TruProfile Interbody Implants:
The SeaSpine Meridian System Interbody assembled with the Anterior Plate, when used with Screws and an Anterior Plate Locking Cover, is a standalone interbody implant 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 spacer component may be packed with autogenous bone graft and/or allogeneic bone graft composed of cancellous, cortical, 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. Hyperlordotic sizes (25 and 30 degrees) are intended for use with 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)

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510(k) Summary

Contact Details

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Contact person:	Jesse Albright, Regulatory Affairs Specialist
Date Prepared:	November 23, 2020

Device Name(s)

Trade Name(s):	SeaSpine Spacer System - (Hollywood NanoMetalene, Hollywood VI NanoMetalene, Ventura NanoMetalene, Pacifica NanoMetalene) SeaSpine Vu a•POD-L NanoMetalene Intervertebral Body Fusion Device SeaSpine Vu e•POD System SeaSpine Vu a•POD Prime NanoMetalene Intervertebral Body Fusion Device Shoreline ACS (Anterior Cervical System) SeaSpine Cambria System SeaSpine Regatta Lateral System Shoreline Cervical Interbody RT System SeaSpine Reef TO/TA System SeaSpine Reef TH System SeaSpine Meridian System
Common Name(s):	Intervertebral body fusion device Spinal intervertebral body fixation orthosis
Classification Name(s):	Intervertebral Fusion Device with Bone Graft, Lumbar (21 CFR 888.3080) Intervertebral Fusion Device with Bone Graft, Cervical (21 CFR 888.3080) Spinal Vertebral Body Replacement Device (21 CFR 888.3060) Intervertebral Fusion Device with Integrated Fixation, Lumbar (21 CFR 888.3080) Intervertebral Fusion Device with Integrated Fixation, Cervical (21 CFR 888.3080)
Class:	II
Product Code(s):	MAX, ODP, MQP, OVD, OVE

Legally Marketed Predicate Devices

510(k) Number	Product Code	Trade Name	Manufacturer
Primary Predicate(s)			
K173260	MAX, ODP, MQP	SeaSpine Spacer System - (Hollywood NanoMetalene, Hollywood VI NanoMetalene, Ventura NanoMetalene, Pacifica NanoMetalene); SeaSpine Vu e•POD System	SeaSpine Orthopedics Corporation
Additional Predicate(s)			
K142488	MAX, ODP	Vu a•POD-L NanoMetalene	SeaSpine Orthopedics Corporation
K173606	OVD	SeaSpine Vu a•POD Prime NanoMetalene Intervertebral Body Fusion Device	SeaSpine Orthopedics Corporation
K201646	OVD	Shoreline ACS (Anterior Cervical System)	SeaSpine Orthopedics Corporation
K171046	ODP	SeaSpine Cambria System	SeaSpine Orthopedics Corporation
K200879	MAX, OVD	SeaSpine Regatta Lateral System; SeaSpine Meridian System	SeaSpine Orthopedics Corporation
K183083	ODP, OVE	Shoreline Cervical Interbody RT System	SeaSpine Orthopedics Corporation
K192132	MAX	SeaSpine Beachside System	SeaSpine Orthopedics Corporation
K193636	MAX	SeaSpine Reef TH System	SeaSpine Orthopedics Corporation
K201267	MAX, OLO	Adaptix Interbody System With Titan NanoLOCK Surface Technology	Medtronic Sofamor Danek
K201605	MAX, ODP	EIT Cellular Titanium® Cervical Cage, EIT Cellular Titanium® ALIF Cage, EIT Cellular Titanium® TLIF Cage, EIT Cellular Titanium® LLIF Cage, EIT Cellular Titanium® T/PLIF Cage	EIT Emerging Implant Technologies GmbH

Device Description

The SeaSpine spacer systems featuring NanoMetalene® surface technology are single-use intervertebral body fusion devices manufactured from polyetheretherketone (PEEK) (per ASTM F2026), tantalum (per ASTM F560) or Ti-6Al-4V ELI (per ASTM F136) markers for radiographic visualization, and NanoMetalene, which is a one-micron thick surface layer of commercially pure

titanium (per ASTM F67). NanoMetalene surface technology provides a microscopic roughened surface with nano-scale features. The devices have a central canal for receiving autogenous bone graft and/or allogeneic bone graft composed of cancellous, cortical, and/or corticocancellous bone and are offered in a variety of sizes and geometries to accommodate variations in pathology and patient anatomy. The purpose of this submission is to describe NanoMetalene surface technology as providing a microscopic roughened surface with nano-scale features and to revise the indications for use with reference to the surface technology.

Indications for Use

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

When used as an intervertebral body fusion device, the SeaSpine Spacer System with NanoMetalene® surface technology 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 and/or allogeneic bone graft composed of cancellous, cortical, and/or corticocancellous bone and supplemental fixation.

SeaSpine Vu a•POD-L NanoMetalene Intervertebral Body Fusion Device

The SeaSpine Vu a•POD-L NanoMetalene Intervertebral Body Fusion Device with NanoMetalene® surface technology 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 to be packed with autogenous bone graft and/or allogeneic bone graft composed of cancellous, cortical, and/or corticocancellous bone. The SeaSpine Vu a•POD-L NanoMetalene Intervertebral Body Fusion Device is intended for use with supplemental fixation that is in addition to the integrated buttress spin plate, such as a pedicle screw system or anterior plate. Degenerative disc disease 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 at least six (6) months of non-operative treatment.

SeaSpine Vu e•POD System

When used as an intervertebral body fusion device, the SeaSpine Vu e•POD System with NanoMetalene® surface technology 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 autogenous bone graft and/or allogeneic bone graft composed of cancellous, cortical, and/or corticocancellous bone. The SeaSpine Vu e•POD System is 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 SeaSpine 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 SeaSpine Vu e•POD 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 autogenous bone graft and/or allogeneic bone graft composed of cancellous, cortical, and/or corticocancellous bone. The SeaSpine Vu e•POD System is intended for use with supplemental internal spinal fixation.

SeaSpine Vu a•POD Prime NanoMetalene Intervertebral Body Fusion Device

When used with the bone screws, the SeaSpine Vu a•POD Prime NanoMetalene Intervertebral Body Fusion Device with NanoMetalene® surface technology 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 composed of cancellous, cortical, and/or corticocancellous bone.

When used with the SpinPlate, 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. 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 composed of cancellous, cortical, and/or corticocancellous bone. When used with the SpinPlate, the SeaSpine Vu a•POD Prime NanoMetalene Intervertebral Body Fusion Device is intended for use with supplemental fixation.

The SeaSpine Vu a•POD Prime NanoMetalene Intervertebral Body Fusion Device, when used with the bone screws or the bone screws and the SpinPlate, is a stand-alone device. If the SeaSpine 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 composed of cancellous, cortical, 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.

Shoreline ACS (Anterior Cervical System)

The Shoreline ACS (Anterior Cervical System) with NanoMetalene® surface technology are interbody fusion devices intended for anterior cervical interbody fusion procedures in skeletally mature patients with degenerative disc disease (DDD) of the cervical spine. DDD is defined as discogenic pain with degeneration of the disc confirmed by history and radiographic studies. The Shoreline ACS implants are to be used with autogenous bone graft and/or allogeneic bone graft composed of cancellous, cortical, and/or corticocancellous bone and implanted via an anterior approach. The device is to be used in patients who have had at least six (6) weeks of non-operative treatment.

When used as a standalone system, Shoreline ACS is intended to be used as an adjunct to spinal fusion procedures at one level (C2-T1) and must be used with the Shoreline ACS bone screw fixation and locking cover.

When used with supplemental fixation, such as anterior cervical plates, the Shoreline Cervical low profile (TruProfile) Interbody Spacer is intended to be used as an adjunct to spinal fusion procedures at one or two levels of the cervical spine (C2-T1).

SeaSpine Cambria System

The SeaSpine Cambria System 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 autogenous bone graft and/or allogeneic bone graft composed of cancellous, cortical, and/or corticocancellous bone and supplemental fixation, such as an anterior plating system.

The SeaSpine Cambria NanoMetalene System with NanoMetalene® surface technology 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 autogenous bone graft and/or allogeneic bone graft composed of cancellous, cortical, and/or corticocancellous bone and supplemental fixation, such as an anterior plating system.

SeaSpine Regatta Lateral System

Interbody Device (IBD) Implants (i.e., interbody implants used alone):
The SeaSpine Regatta Lateral System with NanoMetalene® surface technology is indicated for use as an adjunct to fusion in skeletally mature patients with degenerative disc disease (DDD, defined as back pain of discogenic origin, with degeneration of the disc confirmed by history and radiographic studies). It is intended for use at either one level or two contiguous levels in the lumbar spine, from L2 to S1, for the treatment of DDD with 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 composed of cancellous, cortical, 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.

The SeaSpine Regatta Lateral System is intended for use with supplemental fixation.

TruProfile Interbody Implants:
The SeaSpine Regatta Lateral System assembled with the TruProfile Lateral Plate, when used with Screws, is a standalone interbody implant 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 spacer component may be packed with autogenous bone graft and/or allogeneic bone graft composed of cancellous, cortical, 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.

The SeaSpine Regatta Lateral System assembled with the 1-hole TruProfile Lateral Plate, when used with Screws, is intended for use with supplemental fixation.

Shoreline Cervical Interbody RT System

The Shoreline Cervical Interbody RT System with NanoMetalene® surface technology are interbody fusion devices intended for use in skeletally mature patients with degenerative disc disease (DDD) of the cervical spine (C2-T1) for one or two contiguous levels, depending on the system. DDD is defined as discogenic pain with degeneration of the disc confirmed by history and radiographic studies. These patients should be skeletally mature and have had at least six (6) weeks of non-operative treatment. These devices are to be filled with autogenous bone graft and/or allogeneic bone graft composed of cancellous, cortical, and/or corticocancellous bone.

When used as a standalone system, the Shoreline Cervical Interbody RT System is intended to be used as an adjunct to spinal fusion procedures at a single level (C2-T1) and must be used with the Shoreline ACS bone screw fixation and locking cover.

When used with supplemental fixation, such as anterior cervical plates, the Shoreline Cervical Interbody RT System is intended to be used as an adjunct to spinal fusion procedures at one or two levels of the cervical spine (C3-C7).

When the system is used at two contiguous levels, the Shoreline Cervical Interbody RT System must be used with supplemental fixation.

SeaSpine Reef TO/TA System

When used as an intervertebral body fusion device, the SeaSpine Reef TO/TA System with NanoMetalene® surface technology 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 and/or allogeneic bone graft composed of cancellous, cortical, and/or corticocancellous bone and supplemental fixation.

SeaSpine Reef TH System

The SeaSpine Reef TH System with NanoMetalene® surface technology 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 nonoperative treatment. The device is intended to be used with autogenous bone graft and/or allogeneic bone graft composed of cancellous, cortical, and/or corticocancellous bone and supplemental fixation.

SeaSpine Meridian System

Interbody Device (IBD) Implants (i.e., interbody implants used alone):
The SeaSpine Meridian System with NanoMetalene® surface technology interbody 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 interior of the device is to be used with autogenous bone graft and/or allogeneic bone graft composed of cancellous, cortical, and/or corticocancellous bone. The SeaSpine Meridian Interbody is intended for use with supplemental fixation. Degenerative disc disease 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 at least six (6) months of non-operative treatment.

No-Profile Implants w/ Screws:
The SeaSpine Meridian System No-Profile Interbody, when used with Screws and a No-Profile Locking Cover, is a standalone interbody implant 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 spacer component may be packed with autogenous bone graft and/or allogeneic bone graft composed of cancellous, cortical, 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. Hyperlordotic sizes (25 and 30 degrees) are intended for use with supplemental fixation.

No-Profile Implants w/ Inline Fixation Anchors:
The SeaSpine Meridian System No-Profile Interbody, when used with Inline Fixation Anchors and a No Profile Locking Cover, 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 spacer component may be packed with autogenous bone graft and/or allogeneic bone graft composed of cancellous, cortical, 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. The SeaSpine Meridian No-Profile Implants w/ Inline Fixation Anchors is intended for use with supplemental fixation.

TruProfile Interbody Implants:
The SeaSpine Meridian System Interbody assembled with the Anterior Plate, when used with Screws and an Anterior Plate Locking Cover, is a standalone interbody implant 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 spacer component may be packed with autogenous bone graft and/or allogeneic bone graft composed of cancellous, cortical, 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. Hyperlordotic sizes (25 and 30 degrees) are intended for use with supplemental fixation.

Summary of Technological Characteristics

The subject SeaSpine spacer systems featuring NanoMetalene surface technology are identical to the cited predicate devices in regard to intended use/indications for use, device description, technological characteristics (i.e., operating principle, design, components, materials, sterility, manufacturing, etc.) and non-clinical performance (i.e., mechanical testing).

Non-Clinical Testing

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

Clinical Testing

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

Conclusions

The submitted data demonstrates that the subject SeaSpine Spacer Systems featuring NanoMetalene surface technology are substantially equivalent to the cited legally marketed predicate devices.