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

October 26, 2017

Re: K173022
Trade/Device Name: SeaSpine Ventura NanoMetalene System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: MAX
Dated: September 26, 2017
Received: September 28, 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,

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)*
K173022

Device Name
SeaSpine Ventura NanoMetalene System

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 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.

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

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510(k) Summary **K173022**

Contact Details

Applicant Name: SeaSpine Orthopedics Corporation

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

Date Prepared: October 26, 2017

Device Name

Trade Name: SeaSpine Ventura NanoMetalene System

Common Name: Intervertebral Body Fusion Device

Classification Name: Intervertebral fusion device with bone graft, lumbar (21 CFR 888.3080)

Class: II

Product Code: MAX

Legally Marketed Predicate Devices

510(k) Number	Product Code	Trade Name	Manufacturer
PRIMARY PREDICATE Device			
K162715	MAX	SeaSpine Ventura NanoMetalene-Sterile	SeaSpine Orthopedics Corporation
Additional PREDICATE Devices			
K142488	MAX	SeaSpine Spacer System-NanoMetalene Ventura, Pacifica	SeaSpine Orthopedics Corporation
K082310	MAX	SeaSpine Spacer System-Ventura, Pacifica	SeaSpine Orthopedics Corporation
K102026	MAX	SeaSpine Spacer System-Hollywood	SeaSpine Orthopedics Corporation

Device Description

The SeaSpine Ventura NanoMetalene (NM) System is an intervertebral fusion device manufactured from polyetheretherketone (PEEK) per ASTM F2026 with tantalum markers per ASTM F560 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.

Intended Use/Indications for Use

The SeaSpine Ventura NM subject device has substantially equivalent indications and intended use as the cited predicates:

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.

Summary of Technological Characteristics

The SeaSpine Ventura NM System and predicate devices have the same operating principle; they act as a disc spacer and hold bone graft to promote fusion. The Ventura NM 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

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 Ventura NM System is as safe, as effective, and performs at least as safely and effectively as the cited legally marketed predicate.