Special 510(k) Summary

Company Name: SeaSpine, Inc.
2302 La Mirada Drive
Vista, CA 92081

JAN 27 2011

Contact person: Ethel Bernal
Regulatory Affairs Manager
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Date prepared: November 5, 2010

Trade name: Redondo™/Redondo-L™

Common name: Vertebral Body Replacement Device (VBR)
Interbody Fusion Device (Spacer)

Classification name: Vertebral Body Replacement Device
(21 CFR 888.3060, Product Code MQP, Class II)
(Orthopedic Review Committee)

Spinal Intervertebral Body Fusion Device
(21 CFR 888.3080, Product Code MAX, Class II)
(Orthopedic Review Committee)

Predicate Device: Previously cleared SeaSpine Spacer System 510(k) (K082310)

Device Description: The SeaSpine Spacer System is a family of implantable devices (Hollywood™, Pacifica™, Redondo™/Redondo-L™, Ventura™) manufactured from polyetheretherketone (PEEK) and tantalum radiographic markers. The device has a central canal(s) for receiving bone graft and is offered in a variety of sizes and geometries to accommodate variations in pathology and patient anatomy.

Intended use: When used as an intervertebral body fusion device, the SeaSpine Spacer 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 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 bone graft.

Technological Characteristics:

As was established in the submission, the subject device Redondo-L™ is substantially equivalent to the predicate system. Redondo-L™ devices are manufactured from PEEK OPTIMA® per ASTM F2026 with tantalum markers per ASTM F560 for radiographic visualization. The subject devices have central canals for receiving bone graft and are offered in a variety of sizes and geometries to accommodate variations in pathology and patient anatomy. These materials are identical to materials used to manufacture the predicate devices. The design characteristics are substantially equivalent to the predicate devices.

Performance Data:

Design Controls were used to identify any additional risks introduced by the subject device when compared to the predicate devices. Engineering and Clinical rationale verification methods showed no additional risks with the introduction of the subject footprints to the existing (predicate) product line. See table below for detailed verification activities.

Device Modification	Verification Method	Acceptance Criteria	Results
New cage geometry	Engineering Rationale	Subject device has greater or equivalent cross-sectional area than predicate device.	Accepted
		Subject device has greater or equivalent cross sectional area-to-height Ratio (A/H) than the predicate device.	Accepted
Device maximum foot print	Engineering/Clinical Rationale	Device length is within documented vertebral body dimensions. Increase in implant coverage of larger vertebral bodies minimize stress on endplates and/or local bone, minimizing potential implant subsidence.	Accepted

Device has modified, external "teeth" as compared to the predicate devices.	Engineering Rationale	Teeth on subject device have thicker or equivalent walls than predicate device to provide strength and maximize fixation.	Accepted
		Teeth direction on subject device prevent sublaxation of implant equivalently to the predicate device. Since *in situ* tissue around implant is mostly undisturbed with the exception of the entry site, teeth avoid sublaxation towards the entry site (back out).	Accepted
Device has a different geometry than the predicate devices.	Engineering Rationale	Subject device has greater or equivalent cross-sectional area than predicate device.	Accepted
		Subject device has greater or equivalent wall thickness than predicate device.	Accepted

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

Sea Spine, Inc.
% Ms. Ethel Bernal
Regulatory Affairs Manager
2302 La Mirada Drive
Vista, California 92081-7862

JAN 27 2011

Re: K103297
Trade/Device Name: Redondo™/Redondo-L™
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: MAX, MQP
Dated: January 6, 2011
Received: January 7, 2011

Dear Ms. Bernal:

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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 Small Manufacturers, International and Consumer Assistance 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 yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K103297

Device Name: Redondo™/Redondo-L™

Indications for Use:

When used as an intervertebral body fusion device, the SeaSpine Spacer 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 and supplemental fixation.

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Prescription Use ___X___ AND/OR Over-The-Counter-Use _____

(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED).

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K103297