K082926

510(k) Summary

Company Name:	SeaSpine, Inc. 2302 La Mirada Drive Vista, CA 92081
Contact Person:	Jeff Brittan Senior Project Engineer E-mail: jbrittan@seaspine.com Phone: (760) 727-8399, Fax: (760) 727-8809
Date Prepared:	September 30, 2008
Trade Name:	Zuma™
Common Name:	Interbody Fusion Device Vertebral Body Replacement Device
Classification Name:	Intervertebral Fusion Device with Bone Graft, Lumbar 21 CFR 888.3080, Product Code MAX, Class II Spinal Intervertebral Body Fixation Orthosis 21 CFR 888.3060, Product Code MQP, Class II
Review Panel:	Orthopedic
Device Description:	Zuma is an implantable spinal device made from polyetheretherketone (PEEK) and titanium with markers for radiographic visualization; it is secured to vertebral bodies with bone screws. The device has an open central area for receiving bone graft material 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 Zuma 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. Zuma is a stand alone system intended to be used with the bone screws provided and requires no additional supplementary fixation systems. When used as a Vertebral Body Replacement Device, the Zuma System is intended for use in the thoracolumbar spine (T1 to L5) to replace a

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	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 Zuma 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, Zuma is intended for use with bone graft.
Substantial Equivalence:	Zuma was shown to be substantially equivalent to predicate devices through comparison in areas including intended use, design, materials, and function.
Performance Data:	Mechanical testing results indicated that Zuma possessed appropriate properties for its intended use and is substantially equivalent to predicate devices. Clinical data was not required for this device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

ScaSpine, Inc.
% Mr. Jeff Brittan
Senior Project Engineer
2302 La Mirada Drive
Vista, California 92084

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Re: K082926
Trade/Device Name: Zuma™
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: II
Product Code: MAX, MQP
Dated: September 30, 2008
Received: October 1, 2008

Dear Mr. Brittan:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson

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

Enclosure

Indications for Use

510(k) Number (if known): K082926

Device Name: Zuma™

Indications for Use:

When used as an intervertebral body fusion device, the Zuma 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. Zuma is a stand alone system intended to be used with the bone screws provided and requires no additional supplementary fixation systems.

When used as a Vertebral Body Replacement Device, the Zuma 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 Zuma 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, Zuma is intended for use with bone graft.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David Krause for MKM 12/22/2008

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

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