K071726

Zuma™

510(K) SUMMARY

Submitter Information:	SeaSpine, Inc. 2302 La Mirada Drive Vista, CA 92081-7862 Phone: 760-727-8399 Contact: Ethel Bernal, Regulatory Affairs Manager
Date Summary Prepared:	June 20, 2007
Device Trade Name:	Zuma™
Common/Usual Name:	Vertebral Body Replacement Device
Classification Name:	Spinal Intervertebral Body Fixation Orthosis (MQP, Class II – 21 CFR 888.3060)
Predicate Devices:	SeaSpine VBR System (K052170) Synthes Spine SynFix™-LR System (K062083)

OCT 23 2007

Device Description:

Zuma is a vertebral body replacement device fabricated from PEEK OPTIMA® and titanium. Zuma is designed to restore the biomechanical integrity of the spinal column following full or partial vertebrectomy. The interior of the device is open to provide space for placement of grafting material. Bone screws are inserted through the device into adjacent vertebral bodies. Zuma is available in varying depths, widths, and heights to accommodate variations in patient anatomy.

Intended Use:

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, the Zuma System is intended for use with bone graft.

Performance Data:

Zuma demonstrated sufficient strength in series of mechanical tests.

Substantial Equivalence to Predicate Devices:

Zuma is substantially equivalent to one or more predicate devices listed in this document. Equivalent technological characteristics include design, operating principle, materials of construction, intended use and sterilization methods. Analysis indicated that Zuma is as safe, as effective and performs as well as or better than the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SeaSpine, Inc.
% Mr. Jeff Brittan
Regulatory Affairs Manager
2302 La Mirada Drive
Vista, California 92081-7862

OCT 2 3 2007

Re: K071726
Trade/Device Name: Zuma™
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal intervertebral body fixation orthosis
Regulatory Class: Class II
Product Code: MQP
Dated: September 18, 2007
Received: September 20, 2007

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.

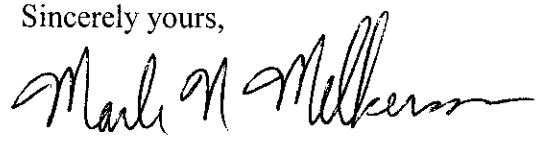
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K071726

Device Name: **Zuma™**

Indications for Use:

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, The Zuma System is intended for use with bone graft.

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

Mark A Melkerson

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

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