510(k) Summary

APR 13 2010

Company Name:	SeaSpine, Inc. 2302 La Mirada Drive Vista, CA 92081
Contact Person:	Ethel Bernal Regulatory Affairs Manager E-mail: ebernal@seaspine.com Phone: (760) 727-8399, Fax: (760) 727-8809
Date Prepared:	August 14, 2009
Trade Name:	Zuma-C™
Common Name:	Interbody Fusion Device
Classification Name:	Intervertebral Body Fusion Device 21 CFR 888.3080, Product Code ODP, Class II Orthopedic Review Committee
Device Description:	Zuma-C is a stand-alone interbody fusion device composed of PEEK and titanium alloy with radiopaque markers, titanium screws and a locking cover. The screws are inserted through the device into adjacent vertebral bodies and the locking cover mates with the device, covering the screws. The device has an open central area for receiving bone graft material and is offered pre-assembled in a variety of heights and geometries to accommodate variations patient anatomy.
Intended Use:	Zuma-C is a stand-alone anterior cervical interbody fusion device intended for use as an adjunct to fusion at one level (C3-C7) in skeletally mature patients with degenerative disc disease (defined as discogenic neck pain with degeneration of the disc confirmed by history and radiographic studies). Patients should have received at least six weeks of non-operative treatment prior to treatment with the device. Zuma-C is to be packed with autogenous bone graft and implanted via an open, anterior approach. Zuma-C is intended to be used with the bone screw fixation provided and requires no additional fixation.
Predicate Devices:	K082309 Cambria™ (SeaSpine, Inc.) K082926 Zuma™ (SeaSpine, Inc.) K072981 Zero-P™ (Synthes Spine)
Technological Characteristics:	Zuma-C was shown to be substantially equivalent to predicate devices through comparison in areas including intended use, design, materials, function and ranges of sizes.

Performance Data: The following pre-clinical studies were conducted using worst case Zuma-C constructs: 1) static and dynamic axial compression, static and dynamic compression shear, and static and dynamic torsion per ASTM F2077; 2) subsidence per ASTM F2267; 3) wear testing per ASTM F2077; and 4) wear debris characterization per ASTM F1714 and ASTM F1877. The results of these studies were found to be substantially equivalent to legally marketed devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

SEP 12 2011

SeaSpine, Inc.
% Ms. Ethel Bernal
Regulatory Affairs Manager
2302 La Mirada Drive
Vista, California 92081

Re: K092521
Trade/Device Name: Zuma-C™
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: OVE
Dated: February 07, 2010
Received: February 12, 2010

Dear Ms. Bernal:

This letter corrects our substantially equivalent letter of April 13, 2010.

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

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

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

510(k) Number (if known): K092521

Device Name: Zuma-C™

Indications for Use:

Zuma-C™ is a stand-alone anterior cervical interbody fusion device intended for use as an adjunct to fusion at one level (C3-C7) in skeletally mature patients with degenerative disc disease (defined as discogenic neck pain with degeneration of the disc confirmed by history and radiographic studies). Patients should have received at least six weeks of non-operative treatment prior to treatment with the device. Zuma-C™ is to be packed with autogenous bone graft and implanted via an open, anterior approach. Zuma-C™ is intended to be used with the bone screw fixation provided and requires no additional fixation.

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)

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

510(k) Number K092521