510(K) SUMMARY

Pursuant to 510(i) of the Federal Food, Drug, and Cosmetic Act, as amended, and in accordance with 21 CFR § 807.92.

Submitter Information:	SeaSpine, Inc. Contact: Diana Smith 2302 La Mirada Drive Vista, CA 92081-7862 Phone: 760-727-8399 Fax: 760-727-8809
Company Registration Number:	2032593
Submission Correspondent:	SeaSpine, Inc. Contact: Diana Smith, Manager of Regulatory Affairs and Quality Assurance 2302 La Mirada Drive Vista, CA 92081-7862 Phone: 760-727-8399 Fax: 760-727-8809
Date Summary Prepared:	September 25, 2006
Classification Name:	**Pedicle Screw Spinal System** MNI (Class II) - 888.3070(b)(1) **Spinal Interlaminal Fixation Orthosis** KWP (Class II) – 888.3050
Common/Usual Name:	Polyaxial screws, rods, locking caps, occipital plates, occipital screws, lateral connectors, crossbars, hooks, components, and instruments
Device Trade Name:	Sierra™

The devices used for comparison in this summary are DePuy Acromed's Summit and Mountaineer OCT Spinal Systems (K002733, K010681, K013222, K022190, K030103, K041203, and K042508), Interpore Cross International's Altius OCT System (K022048, K033961, and K043229), and Medtronic Sofamor Danek's Vertex Reconstructive System (K003780, K022015, K023555, K042402, K042498, K042524, K052180, K052376, K052734, and K053483).

1. **Intended Use:** (The statements of intended use are identical.)

The intended use of the **Sierra** spinal system is to promote fusion of the cervical spine and occipito-cervico-thoracic junction (occiput-T3). The indications for use are as follows:

- degenerative disc disease (DDD) as defined by back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies,
- spondylolisthesis,
- trauma (*i.e.*, fracture or dislocation),
- spinal stenosis,
- atlantoaxial fracture with instability,
- occipitocervical dislocation,
- revision of previous cervical spine surgery, and/or
- spinal tumor.

The occipital bone screws are limited to occipital fixation only.

The use of the polyaxial screws is limited to placement in the upper thoracic spine (T1-T3) in treating thoracic conditions only. They are not intended to be placed in the cervical spine.

2. **Description:**

The Sierra spinal system will include polyaxial screws, rods, locking caps, occipital plates, occipital screws, lateral connectors, crossbars, hooks, and components. All products are fabricated from titanium alloy, with the exception of the screws which have a cobalt alloy component, and are being offered in a wide variety of sizes. All product is supplied "NON-STERILE" and must be sterilized prior to use.

Sierra will also offer a wide variety of instruments that range from bone awls to occipital screwdrivers. These instruments will be made from various grades of stainless steel with Radel and aluminum alloy being used in a few handles. All items are supplied "NON-STERILE" and must be sterilized prior to use.

3. **Technological Characteristics:**

The various implants and instruments in this notification are components of SeaSpine's new stand alone OCT spinal fixation system called, Sierra. The devices in this submission have substantially equivalent technological characteristics to the predicate devices. Refer to **Table 1** in the following section, entitled *Comparison Analysis*, for a summation of technological characteristics such as design, dimensional specifications, and material.

4. Comparison Analysis:

The overall designs of the polyaxial screws, rods, locking caps, occipital plates, occipital screws, lateral connectors, crossbars, hooks, and components in this submission are substantially equivalent to the predicate devices. See **Table 1** on the following page for a comparison of the Sierra polyaxial screws, rods, locking caps, occipital components, lateral connectors, contoured crossbars, hooks, and components to the predicate devices.

Feature	Sierra	DePuy Acromed's Summit and Mountaineer OCT Spinal Systems	Interpore Cross International's Altius OCT System	Medtronic Sofamor Danek's Vertex Reconstructive System	Substantially Equivalent
Intended Use	The intended use of the **Sierra** spinal system is to promote fusion of the cervical spine and occipito-cervico-thoracic junction (occiput-T3).	Similar	Similar	Similar	Yes
Indications for Use	•degenerative disc disease (DDD) as defined by back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies, •spondylolisthesis, •trauma (*i.e.*, fracture or dislocation), •spinal stenosis, •atlantoaxial fracture with instability, •occipitocervical dislocation, •revision of previous cervical spine surgery, and/or •spinal tumor.	Similar	Similar	Similar	Yes
Design	Polyaxial screws, rods, locking caps, occipital plates, occipital screws, lateral connectors, crossbars, hooks, and components.	Similar	Similar	Similar	Yes
Polyaxial Screws	Various sizes.	Similar	Similar	Similar	Yes
Locking Cap	Various sizes.	Similar	Similar	Similar	Yes
Lateral Connectors	Various sizes.	Similar	Similar	Similar	Yes
Crossbars	Various sizes.	Similar	Similar	Similar	Yes
Occipital Plates	Various sizes.	Similar	Similar	Similar	Yes
Occipital Screws	Various sizes.	Similar	Similar	Similar	Yes
Hooks	Various sizes.	Similar	Similar	Similar	Yes
Rods	Various sizes.	Similar	Similar	Similar	Yes
Material	Titanium alloy and cobalt alloy.	Similar	Similar	Similar	Yes
Sterile	Non-sterile	Similar	Similar	Similar	Yes
Method of Sterilization	High-temperature steam	Similar	Similar	Similar	Yes
Mechanical Strength	All products passed testing per applicable standards.	Similar	Similar	Similar	Yes

Table 1: Summary of Design Comparison

(i) A financial certification or disclosure statement or both, as required by part 54 of this chapter:

A financial certification and/or disclosure statement is not needed for this submission as no clinical studies have been undertaken in regards to the products under consideration.

(j) For submission claiming substantial equivalence to a device which has been classified into class III under section 513(b) of the act:

(1) Which was introduced or delivered for introduction into interstate commerce for commercial distribution before December 1, 1990: and

(2) For which no final regulation requiring premarket approval has been issued under section 515(b) of the act, a summary of the types of safety and effectiveness problems associated with the type of devices being compared and a citation to the information upon which the summary is based (class III Summary). The 510(K) submitter shall also certify that a reasonable search of all information known or otherwise available about the class III device and other similar legally marketed devices has been conducted (Class III Certification), as described in Sec. 807.94.

A *Premarket Notification Class III Certification and Summary* is not needed for this submission as the products under consideration are class II.

(k) A statement that the submitter believes, to the best of his or her knowledge, that all data and information submitted in the Premarket notification are truthful and accurate and that no material fact has been omitted.

A ***Premarket Notification Truthful and Accurate Statement*** is included on the following page.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SeaSpine, Inc.
% Ms. Ethel Bernal
Document Control Specialist
2302 La Mirada Drive
Vista, California 92081-7862

NOV 16 2006

Re: K062934
Trade/Device Name: SIERRA
Regulation Number: 21 CFR 888.3070, 888.3050
Regulation Name: Pedicle Screw Spinal System, Spinal interlaminal fixation orthosis
Regulatory Class: Class II
Product Code: MNI, KWP
Dated: September 25, 2006
Received: September 28, 2006

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.

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 Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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 (240) 276-3150 or at its 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): _____

Device Name: Sierra

Indications for Use:

The intended use of the **Sierra** spinal system is to promote fusion of the cervical spine and occipito-cervico-thoracic junction (occiput-T3). The indications for use are as follows:

- degenerative disc disease (DDD) as defined by neck pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies,
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- occipitocervical dislocation,
- revision of previous cervical spine surgery, and/or
- spinal tumor.

The occipital bone screws are limited to occipital fixation only.

The use of the polyaxial screws is limited to placement in the upper thoracic spine (T1-T3) in treating thoracic conditions only. They are not intended to be placed in the cervical spine.

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).

(Division Sign-Off)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division of General, Restorative, and Neurological Devices

510(k) Number k062934