

Special 510(k) Summary

Submitter: SeaSpine Inc.
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Contact person: Ethel Bernal, Regulatory Affairs Manager

Date prepared: September 25, 2007

Trade name: Sierra™

Common name: Rod connectors, crossbars, set screws

Classification name: Spinal Interlaminar Fixation Orthosis
KWP (Class II) – 888.3050

Substantial equivalence claimed to:

The devices used for comparison in this summary are SeaSpine, Inc.'s Sierra Spinal System (K062934) and Interpore Cross International's Altius OCT System (K022048, K033961 and K043229).

The overall designs of the rod connectors, crossbars and set screws in this submission are substantially equivalent to the predicate devices.

Description:

Rod connectors, crossbars and set screws are being added to the Sierra spinal system. All products are fabricated from titanium alloy. All products are supplied "NON-STERILE" and must be sterilized prior to use.

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 neck 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,

Sierra™

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- 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.

Summary of technological characteristics:

The rod connectors, crossbars and set screws in this notification are components of ScaSpine's stand alone occipito-cervico-thoracic spinal fixation system called Sierra. The addition of the new devices has not altered the fundamental scientific technology of the previously cleared system. The devices in this submission have substantially equivalent technological characteristics to the predicate devices.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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

APR 17 2008

Re: K072729
Trade/Device Name: Sierra™
Regulation Number: 21 CFR 888.3050
Regulation Name: Spinal interlaminar fixation orthosis
Regulatory Class: II
Product Code: KWP
Dated: April 14, 2008
Received: April 19, 2008

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.

Page 2 – Ms. Ethel Bernal

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): K072729

Device Name: Sierra

Indications for Use:

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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)

Nick G. Gorman
(Division Sign-Off)
Division of General, Restorative,
and Neurological Devices

510(k) Number K072729