NOV 2 0 2003



## SPECIAL 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: Kirt Stephenson
6276 River Crest Drive, Suite E
Riverside, CA 92507-0754
Phone: 909-656-4850 Fax: 909-656-5530

**Company Registration Number:** 2032593

**Submission Correspondent:**

The Regulatory Affairs Company
Contact: Diana Smith
727 Park Boulevard
San Diego, CA 92101
Phone: 619-251-9132 Fax: 619-696-9883

**Date Summary Prepared:** August 18, 2003

**Classification Name:**

Spondylolisthesis Spinal Fixation Device System (Class II) – MNH 888-3070
Pedicle Screw Spinal System (Class II) – MNI 888-3070
Spinal Interlaminal Fracture Orthosis (Class II) – KWP 88-3050

**Common/Usual Name:** Variable and Fixed Cross Link System

**Device Trade Name:** UCR Spinal System

The primary device used for comparison in this summary is SeaSpine Inc.'s existing UCR Spinal System cross links (K993503, K021623, and K031381).

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

The intended use and indications when used as a **Spondylolisthesis Spinal Fixation Device System** are:

- **The UCR Spinal System** is a pedicle screw system indicated for the treatment of severe spondylolisthesis (Grades 3 and 4) of the L5-S1 vertebra in skeletally mature patients receiving fusions by autogenous bone graft having implants attached to the lumbar and sacral spine (L3 to sacrum) with removal of the implants after the attainment of a solid fusion.

The intended use and indications when used as a **Pedicle Screw Spinal System** are:

- **The UCR Spinal System** is a pedicle screw system intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar, and sacral spine:
- degenerative spondylolisthesis with objective evidence of neurological impairment,
- fracture,
- dislocation,
- scoliosis,
- kyphosis,
- spinal tumor, and
- failed previous fusion (pseudoarthrosis).

The indications for use as a **Hook Spinal System** are limited to T1-L5 and are:

- degenerative disc disease (as defined by back pain of discogenic origin with degeneration of the disc confirmed by patient history ad radiographic),
- spinal stenosis,
- spondylolisthesis,
- spinal deformities (scoliosis, kyphosis, and/or lordosis),
- fracture,
- pseudarthosis,
- tumor resection, and/or
- failed previous fusion.

## 2. Description:

The UCR Spinal System cross links and their components include variable and fixed cross links, fixed cross link bars, link bars, rounded links, screws, coupler, and an instrument. The variable cross links will be available in sizes ranging from 23 to 75mm and the fixed cross links and fixed cross link bars in sizes between 20 and 36mm. The product is supplied "NON-STERILE" and must be sterilized prior to use.

## 3. Technological Characteristics:

The UCR Spinal System variable and fixed cross links have substantially equivalent technological characteristics to the predicate device. 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 design of the UCR Spinal System fixed and variable cross links and their components is essentially the same as that of the predicate device. See **Table 1** bon the following page for a comparison of the fixed and variable cross link system and the predicate device.

| PREDICATE DEVICE COMPARISON SUMMARY TABLE | | | |
|---|---|---|---|
| **Feature** | **Variable and Fixed Cross Link System** | **Approved Cross Link** | **Substantially Equivalent** |
| Intended Use | See Instructions for Use | Identical | Yes |
| Indications for Use | See Instructions for Use | Identical | Yes |
| Design and Scientific Technology | Titanium cross bar which clamps onto spinal rods to reduce the chance of movement to aid fusion. Uses a 3mm manual hex driver to lock the device. | Identical | Yes |
| Sizes | See prints | 60, 70, 80 mm | Yes, with additional sizes |
| Material | Titanium alloy | Identical | Yes |
| Sterile | Non-sterile | Identical | Yes |
| Mechanical Strength | See test results | Similar | Yes |

**Table 1:** Summary of Design Comparison

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 2 0 2003

SeaSpine, Incorporated
C/o Ms. Diana Smith
The Regulatory Affairs Company
727 Park Boulevard
San Diego, California 92101

Re: K032739/S1
Trade/Device Name: UCR Spinal System
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle screw spinal system
Regulatory Class: II
Product Code: MNI, MNH
Dated: October 15, 2003
Received: October 21, 2003

Dear Ms. Smith:

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 (301) 594-4659. 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 (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Miriam C. Provost

for Celia M. Witten, Ph.D., M.D.
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): K032739 (A1)

Device Name: UCR Spinal System

The intended use of the UCR Spinal System variable and fixed cross links remains the same as that of the existing variable and fixed cross links.

The intended use and indications when used as a **Spondylolisthesis Spinal Fixation Device System** are:

- **The UCR Spinal System** is a pedicle screw system indicated for the treatment of severe spondylolisthesis (Grades 3 and 4) of the L5-S1 vertebra in skeletally mature patients receiving fusions by autogenous bone graft having implants attached to the lumbar and sacral spine (L3 to sacrum) with removal of the implants after the attainment of a solid fusion.

The intended use and indications when used as a **Pedicle Screw Spinal System** are:

- **The UCR Spinal System** is a pedicle screw system intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar, and sacral spine:
- degenerative spondylolisthesis with objective evidence of neurological impairment,
- fracture,
- dislocation,
- scoliosis,
- kyphosis,
- spinal tumor, and
- failed previous fusion (pseudoarthrosis).

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED).

Concurrence of CDRH, Office of Device Evaluation (ODE)

Miriam C. Provost

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

Prescription Use ✓ 510(k) Number OR ~~Over-The-Counter-Use~~ K032739
(Per 21 CFR § 801.109)