K021623 p1/3

SEP 1 0 2002

Summary of Safety and Effectiveness Information *Premarket Notification, Section 510(k)*	SEASPINE, INC. AUGUST 23, 2002

Regulatory Authority: Safe Medical Devices Act of 1990, 21 CFR 807.92

1. Device Name:

Trade Name: **UCR Spinal System**
Common Name(s): pedicle screw
Classification Name(s): Pedicle Screw Spinal System (Class II Uses)

2. Establishment Name & Registration Number:

Name: SEASPINE, INC.
Number:

3. Classification:

§ 888.3070 – Spondylolisthesis Spinal Fixation Device System
§ 888.3070 – Pedicle Screw Spinal System (Class II Uses)

Device Class: Class II for the requested indications
Classification Panel: Orthopaedic and Rehabilitation Devices Panel
Product Code(s): MNH, MNI, respectively

4. Equivalent Predicate Device:

The *5.5mm Spinal Screws* may be directly contrasted with the larger diameter cleared spinal screws of *UCR Spinal System, K983353.* Other than the reduced major screw diameter, the new Spinal Screws are essentially the same as the cleared spinal screws in the existing *UCR Spinal System.* The basic design, dimensional tolerances, materials and intended use are identical.

5. Device Description:

The new 5.5mm screw will be used in all *UCR Spinal System* applications where a smaller screw would be of benefit. Therefore, the mechanical properties and fatigue performance are important. The remainder of the *UCR Spinal System* components will remain unchanged. Other than the major and minor diameter of the cancellous portion of the shaft and threads, the new 5.5mm screws are similar to the existing screws. Spinal rod attachment method are the same as cleared previously.

The new 8.0mm Spinal Screws expand the options for screw insertion by providing an alternative to the smaller 6, 6.5 or 7.0mm pedicle screws of the available *UCR Spinal System.* This new screw diameter allows the surgeon to insert screws in cases where the spine deformity or the large size of the pedicle makes use of smaller diameter screws less desirable. The larger diameter of the 8.0mm Spinal Screws permits the surgeon to address the needs of an expanded patient population.

Testing Summary:

Mechanical and fatigue testing were carried out. Samples were tested using the ASTM F-1717-96 guidance document. Both the 505mm and the 8.0mm pedicular screws carry clinically useful loads out to the five-million cycle asymptotic endurance limit.

Indications for Use:

Indicated for the treatment of severe spondylolisthesis (Grades 3 and 4) of the L5-S1 vertebra in skeletally mature patients receiving fusion 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. Also 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 (pseudarthrosis)

6. Applicant Name & Address:

SEASPINE, INC.
6276 River Crest Drive
Riverside, CA 92507.0754
909.413.0200 (v) 909.653.5680 (f)

7. Company Contact:

Regulatory Affairs
6276 River Crest Drive
Riverside, CA 92507.0754
909.413.0200 (v) 909.653.5680 (f)

8. Submission Correspondent:

Mr. David W. Schlerf
Buckman Company, LLC.
200 Gregory Lane, Suite C-100
Pleasant Hill, CA 94523-3389
925.356.2640 - 925.356.2654 - fax

9. Performance Standards:

United States Food and Drug Administration mandated performance standards for this device do not exist. Various voluntary performance standards are utilized. Voluntary standards utilized include ASTM, Standard Operating Procedures, vendor & process certification and qualification procedures, Quality Systems Regulations, ISO materials standards and ISO 9000 series quality regulations. *SEASPINE, INC.* In addition, meets appropriate general controls authorized under Sections 501, 502, 510, 516, 518, 519, and 520 of the Food, Drug, and Cosmetic Act.

10. Special Controls:

Special controls were published in the Federal Register, Vol. 63, No. 143, July 27, 1998 (Orthopedic Devices: Classification and Reclassification of Pedicle Screw Spinal Systems). The following special controls apply to the marketing of this device when used as a posterior pedicle system:

(i) Compliance with material standards,
(ii) Compliance with mechanical testing standard,
(iii) Compliance with biocompatability standard, and
(iv) Compliance with specified labeling requirements.

11. Special Guidance Document Information:

The 510(k) was prepared in accordance with:

- "Guidance for Spinal System 510(k)'s," May 7, 1999.
- "The New 510(k) Paradigm, Alternate Approaches to Demonstrating Substantial Equivalence in Premarket Notifications - Final Guidance, March 20, 1998.

12. Storage, Packaging & Sterilization Information:

The *UCR Spinal System* is supplied *"NON-STERILE"* and must be sterilized before use. The recommended sterilization process is high temperature steam autoclave sterilization. The recommended sterilization cycle will produce a Sterility Assurance Level (SAL) of at least 10^{-6}.

The validated sterilization cycle is:

Method:	Steam
Cycle:	Gravity
Temperature:	270°F (134°C)
Exposure Time:	30 minutes

13. Summary Comparison Table:

FEATURE	*SeaSpine UCR Spinal Screws*	*UCR Spinal System*	SE?
Indications for Use:	Indicated for the treatment of severe spondylolisthesis (Grades 3 and 4) of the L5-S1 vertebra in skeletally mature patients receiving fusion 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. Also 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 pseudarthrosis)	Identical	YES
Design:	Cancellous thread pedicle screw, vertebral screws, sacral screws, Polyaxial	SAME	YES
Sterile:	Non-sterile	SAME	YES
Sizes:	5.5 & 8.0mm diameter in 35, 40 and 45mm lengths	EQUIVALENT	YES
Material:	Titanium alloy	Identical	YES
Manufacturer:	SeaSpine, Inc.	IAME, Inc.	YES
Product Code:	MNH, MNI	SAME	YES
K - Number:	K021623	K993503	YES

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 1 0 2002

SeaSpine, Inc.
c/o Mr. David W. Schlerf
Buckman Company, Inc.
200 Gregory Lane, Suite C-100
Pleasant Hill, California 94523

Re: K021623
Trade/Device Name: UCR Spinal System
Regulatory Number: 21 CFR 888.3070
Regulation Name: Pedicle screw spinal system,
Regulatory Class: II
Product Code: MNH, MNI
Dated: August 15, 2002
Received: August 16, 2002

Dear Mr. Schlerf:

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.

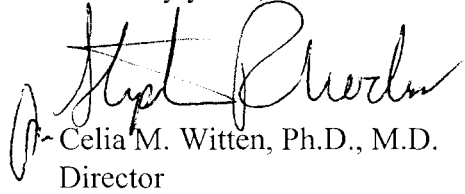
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained 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,



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

510(k) Number : K021623

Device Name(s): ***5.5mm, 8.0mm Spinal Screws and Instruments***
(Haider UCR Spinal System)

Intended Use(s) of the Device:

1. **Spondylolisthesis Spinal Fixation Device System, 87MNH** the intended use and indications for use are:

- The ***HAIDER-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 fusion 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.

2. **Pedicle Screw Spinal System**, (Class II uses) **87MNI** the intended use and indications for use are:

- The ***HAIDER-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 pseudarthrosis).

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Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number K021623

Prescription Use X OR Over-The-Counter Use _____(Per 21 CFR 801.109)
(Optional format 1-2-96)