K072605

5. 510(K) SUMMARY

Submitter Information:

SeaSpine, Inc.
2302 La Mirada Drive
Vista, CA 92081-7862
Phone: 760-727-8399
Contact: Ethel Bernal, Regulatory Affairs Manager

DEC 2 0 2007

Date Summary Prepared: September 14, 2007

Device Trade Name: Malibu Spinal System

Common/Usual Name: Spinal rod, Sublaminar Wire, Cap, Set Screw

Classification Name:

Pedicle Screw Spinal System
MNH (Class II) – 888.3070(b)(1)
MNI (Class II) – 888.3070(b)(1)
NKB (Class III) – 888.3070(b)(2)

Spinal Interlaminal Fixation Orthosis
KWP (Class II) – 888.3050

Predicate Devices:

SeaSpine, Malibu Spinal System (K061342, K051942, K051663)
Medtronic Sofamor Danek, MSD Wire System (K020426)
Stryker Spine, Xia Spinal System (K060979)

Device Description:

The system contains titanium alloy and cobalt alloy implants. This submission is intended to address the line extensions including titanium and cobalt alloy spinal rods, cap, set screw, and a sublaminar wire. All devices are supplied non-sterile. These devices are not compatible with stainless steel implants.

Intended Use:

1. The intended use of the **Malibu system,** when used as a **Pedicle Screw Spinal System or Spondylolisthesis Spinal Fixation Device System**, is 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. 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,
   - 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 (indication for use only when used as a Spondylolisthesis Spinal Fixation Device System),
   - spondylolisthesis,
   - trauma (*i.e.*, fracture or dislocation),
   - spinal stenosis,
   - deformities or curvatures (*i.e.*, scoliosis, kyphosis, and/or lordosis),

- spinal tumor,
- pseudoarthrosis, and/or
- failed previous fusion.
-

2. The intended use and indications of the **Malibu system,** when used as a **Spinal Interlaminal Fixation Orthosis or Hook Spinal System or Sublaminar Wire System,** are limited to T1-L5 and 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,
   - deformities or curvatures (*i.e.*, scoliosis, kyphosis, and/or lordosis),
   - tumor,
   - pseudarthosis, and/or
   - failed previous fusion.

Performance Data:

The devices were justified or mechanically tested to substantiate comparable mechanical properties to the predicate devices.

Substantial Equivalence to Predicate Devices:

The Malibu Spinal System line additions are substantially equivalent to one or more predicate devices listed in this document. Equivalent technological characteristics include design, operating principle, materials of construction, intended use and sterilization methods. The analysis indicates that the line additions are as safe, as effective and perform as well as or better than the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 2 0 2007

SeaSpine, Inc.
% Ms. Ethel Bernal
Regulatory Affairs Manager
2302 La Mirada Drive
Vista, CA 92081-7862

Re: K072605
Trade/Device Name: Malibu Spinal System
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle Screw Spinal System
Regulatory Class: III
Product Code: NKB, MNI, MNH, KWP
Dated: December 4, 2007
Received: December 4, 2007

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 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

2. Indications for Use Statement

510(k) Number (if known): K072605

Device Name: **Malibu Spinal System**

Indications for Use:

1. The intended use of the **Malibu system,** when used as a **Pedicle Screw Spinal System or Spondylolisthesis Spinal Fixation Device System**, is 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. The indications for use are as follows:
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   - spondylolisthesis,
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   - spinal stenosis,
   - deformities or curvatures (*i.e.*, scoliosis, kyphosis, and/or lordosis),
   - spinal tumor,
   - pseudoarthrosis, and/or
   - failed previous fusion.

Prescription Use ___X___ AND/OR Over-The-Counter-Use _____
(Part 21 CFR 801 Subpart D) (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)

Barbara Bonehm for MKM

(Division Sign-Off)

Division of General, Restorative, and Neurological Devices

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2. The intended use and indications of the **Malibu system,** when used as a **Spinal Interlaminal Fixation Orthosis or Hook Spinal System or Sublaminar Wire System,** are limited to T1-L5 and 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,
   - deformities or curvatures (*i.e.*, scoliosis, kyphosis, and/or lordosis),
   - tumor,
   - pseudarthosis, and/or
   - failed previous fusion.

Prescription Use ___X___ AND/OR Over-The-Counter-Use _____
(Part 21 CFR 801 Subpart D) (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)

Barbara Buehrig

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

510(k) Number K072605