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JUL 23 2008

510(k) Summary
for the Spineworks FixxSure Cross Link

In accordance with 21 CFR 807.92 of the Federal Code of Regulations
the following 510(k) summary is submitted for the SpineWorks FixxSure Cross Link.

Date Prepared: May 7, 2008

1. **Submitter:**
SpineWorks LLC
16742 Gothard St. Suite 101
Huntington Beach, CA 92647

Contact Person:
J.D. Webb
The OrthoMedix Group, Inc.
1001 Oakwood Blvd
Round Rock, TX 78681
Telephone: 512-388-0199

2. **Trade name:** FixxSure Cross Link
Common Name: pedicle screw system crosslink
Classification Name: Pedicle screw spinal system
Class II
21 CFR 888.3070
MNI/MNH

3. **Predicate or legally marketed devices which are substantially equivalent:**
Sea Spine Crossbar (K032739)
Acme/Talon Pedicle Screw system (K071824).

4. **Description of the device:**
The SpineWorks FixxSure Cross Link allows spinal surgeons to convert a dual-rod construct into a frame and increase overall construct strength. The FixxSure Cross Link comes in a multi-span and fixed design, both of which can be rigidly locked onto a dual-rod construct and has the capability of being manipulated into various planes of angulation. The SpineWorks implant has a proprietary dual locking mechanism allowing maximum Cross Link/rod connection while offering superior ease of insertion/use.

Materials:
The components in this submission are fabricated from Ti6Al4V alloy, conforming to ASTM F136, which is known to have good biocompatibility.

Function:
Cross Link systems were introduced to increase the rigidity of the pedicle screw constructs.

5. **Intended Use:**
The SpineWorks FixxSure Cross Link is intended work with the Talon Pedicle Screw system 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 thoracic, lumbar, and sacral spine: severe spondylolisthesis (grades 3 and 4) of the L5-S1 vertebra; degenerative spondylolisthesis with objective evidence of neurologic impairment; fracture; dislocation; scoliosis; kyphosis; spinal tumor; and failed previous fusion (pseudarthrosis).

The SpineWorks FixxSure Cross Link must be used with the Talon Pedicle Screw system.

6. **Comparison of the technological characteristics of the device to predicate and legally marketed devices:**

   The FixxSure Cross Link is similar to the predicate device in terms of material, design and indications.

7. **Summary of Nonclincal Tests**

   Testing was conducted according to ASTM F1717 and F1798 with adequate strength.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SpineWorks, LLC.
% OrthoMedix Group, Inc.
Mr. J.D. Webb
1001 Oakwood Boulevard
Round Rock, TX 78681

JUL 23 2008

Dear Mr. Webb:

Re: K081331
Trade/Device Name: FixxSure Cross Link
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle screw spinal system
Regulatory Class: Class II
Product Code: MNH, MNI
Dated: May 7, 2008
Received: May 12, 2008

Dear Mr. Webb:

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

Indications for Use

510(k) Number (if known): K081331

Device Name: SpineWorks FixxSure Cross Link

Indications for Use:

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The SpineWorks FixxSure Cross Link must be used with the Talon Pedicle Screw system.

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 OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number K081331