

**510(k) SUMMARY****Lanx Spinal Fixation System****OCT 9 0 2009****Submitter Information**

Name and Address: Lanx, Inc.  
 390 Interlocken Crescent, Suite 890  
 Broomfield, CO 80021

Contact Person: Andrew Lamborne

Date Prepared: August 14, 2009

**Device Identification**

Proprietary Name: Lanx Spinal Fixation System

Common Name: Spinal Fixation System

Classification: Pedicle Screw Spinal System 21 CFR 888.3070 and/or Spinal Interlaminar Fixation Orthosis 21 CFR 888.3050

Product Codes: MNI, MNH, KWP, NKB

**Predicate Device Information**

Lanx Spinal Fixation System, Lanx, Inc.

Stryker Spine Xia 3 Spinal System, Stryker Spine

Expedium Spine System, DePuy Spine, Inc.

**Intended Use / Indications for Use**

The Lanx Spinal Fixation System (SFS) is intended to be used to help provide immobilization and stabilization of spinal segments as an adjunct to fusion of the thoracic, lumbar and/or sacral spine. The System is intended for use with autograft or allograft.

The Lanx Spinal Fixation System is intended for posterior, non-cervical (T1-S2/ilium) pedicle and non-pedicle spinal fixation, to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following instabilities or deformities: degenerative disc disease (DDD, defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies); spondylolisthesis; trauma (i.e. fracture or dislocation); spinal stenosis; deformities or curvatures (i.e. scoliosis, kyphosis and/or lordosis); tumor; pseudoarthrosis; and failed previous fusion.

**Technological Characteristics**

The Lanx Spinal Fixation System consists of various screws, hooks, rods, plates, connectors, etc. that are used to build a construct to provide supplemental stabilization of spinal segments to support fusion. The system components can be assembled in a variety of configurations, allowing the surgeon to tailor the construct to the particular needs of the patient.

**Performance Data**

Performance testing and engineering analysis was performed and submitted to characterize the system. The Lanx Spinal Fixation System functioned as intended and the observed test results demonstrate substantial equivalence to the predicate device.

**Substantial Equivalence**

The modified Lanx Spinal Fixation System is as safe and effective as the predicate devices. The Lanx Spinal Fixation System has the same intended use, indications, technological characteristics, and principles of operation as the predicate systems. The modifications do not raise any new issues of safety or effectiveness. Thus, the modified Lanx Spinal Fixation System is substantially equivalent to the predicate devices.



Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Room W-O66-0609  
Silver Spring, MD 20993-0002

**OCT 30 2009**

Lanx, Inc.  
% Hogan & Hartson LLP  
Ms. Janice M. Hogan  
Regulatory Counsel  
1835 Market Street  
Suite 2820  
Philadelphia, Pennsylvania 19103

Re: K092536

Trade/Device Name: Lanx Spinal Fixation System  
Regulation Number: 21 CFR 888.3070  
Regulation Name: Pedicle screw spinal system  
Regulatory Class: Class III  
Product Code: NKB, KWP, MNH, MNI  
Dated: August 14, 2009  
Received: August 19, 2009

Dear Ms. Hogan:

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 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); medical device reporting (reporting of medical

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device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/cdrh/mdr/> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Mark N. Melkerson  
Director  
Division of Surgical, Orthopedic  
and Restorative Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

**Indications for Use Statement**

510(k) Number (if known):

Device Name: Lanx Spinal Fixation System

Indications for Use:

The Lanx Spinal Fixation System (SFS) is intended to be used to help provide immobilization and stabilization of spinal segments as an adjunct to fusion of the thoracic, lumbar and/or sacral spine. The System is intended for use with autograft or allograft.

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Prescription Use  X   
(Part 21 CFR 801 Subpart D)

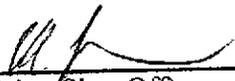
AND/OR

Over-The-Counter Use \_\_\_\_\_  
(21 CFR 801 Subpart C)

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

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Concurrence of CDRH, Office of Device Evaluation (ODE)

  
\_\_\_\_\_  
(Division Sign-Off)  
Division of Surgical, Orthopedic,  
and Restorative Devices

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