K103660

FEB 2 8 2011

510(k) SUMMARY

Lanx Intervertebral Body/VBR Fusion System

Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared

Lanx, Inc.
390 Interlocken Crescent, Suite 890
Broomfield, CO 80021

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Contact Person: William Sandul
Date Prepared: December 14, 2010

Name of Device and Name/Address of Sponsor

Lanx Fusion System

Lanx, Inc.
390 Interlocken Crescent, Suite 890
Broomfield, CO 80021

Common or Usual Name

Intervertebral Body/VBR Fusion System

Classification Name

21 CFR 888.3080 - Intervertebral Body Fusion Device
21 CFR 888.3060 - Spinal Intervertebral Body Fixation Orthosis

Predicate Device(s)

Lanx Intervertebral Body/VBR Fusion System (K083815)
LDR Spine MC+ Cervical Interbody Fusion System (K091088)
Spinal Elements Crystal Cervical Cage System (K073351)

Description of Device Modification

This submission is intended to seek clearance for a product line extension to the Lanx Intervertebral Body/VBR Fusion System ("Lanx Fusion System"). The product line extension includes additional cervical intervertebral body fusion device implants with increased graft volume, additional larger implant footprints, implants with a convex superior endplate, and modifications to accommodate a threaded inserter.

All implants in the Lanx Fusion System are manufactured from PEEK-OPTIMA® LT1 per ASTM F2026, titanium alloy (Ti-6Al-4V) per ASTM F136, and tantalum per ASTM F560. The implants have a hollowed out area to accommodate autogenous bone graft, and transverse grooves to improve fixation and stability. The implants are offered in a variety of footprints and heights to accommodate anatomical variation in different vertebral levels and/or patient anatomy. The Lanx Fusion System is provided non-sterile.

Statement of Technological Comparison

The additional cervical intervertebral body fusion device implants have the same intended use and indications, principles of operation, and technological characteristics as the cervical intervertebral body fusion device implants of the previously-cleared Lanx Fusion System. The minor differences between the modified and previously-cleared systems do not raise any new issues related to safety or efficacy. Mechanical testing demonstrated comparable mechanical properties between the modified and predicate devices.

Intended Use / Indications for Use

When used as a cervical intervertebral body fusion device, the Lanx Intervertebral Body/VBR Fusion System ("Lanx Fusion System") is intended for spinal fusion procedures to be used with autogenous bone graft in skeletally mature patients with degenerative disc disease ("DDD") at one spinal level from the C2-C3 disc to the C7-T1 disc. DDD is defined as neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. These patients should have had at least six weeks of non-operative treatment. The Lanx Cervical Intervertebral Body Fusion System is to be implanted via an anterior approach and is to be combined with supplemental fixation. Approved supplemental fixation systems include the Lanx Anterior Cervical Plate System.

When used as a lumbar intervertebral body fusion device, the Lanx Intervertebral Body/VBR Fusion System ("Lanx Fusion System") is intended for spinal fusion procedures to be used with autogenous bone graft in skeletally mature patients with degenerative disc disease ("DDD") at one or two contiguous spinal levels from L2-S1. DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. These patients should have had six months of non-operative treatment. These DDD patients may have had a previous non-fusion spinal surgery at the involved spinal level(s), and may have up to Grade 1 spondylolisthesis or retrolisthesis at the involved level(s). The Lanx Fusion System is to be implanted via an anterior or posterior approach and is to be combined with supplemental fixation. Approved supplemental fixation systems include the Lanx Spinal Fixation System.

When used as vertebral body replacement, the Lanx Intervertebral Body/VBR Fusion System ("Lanx Fusion System") is indicated for use to replace a vertebral body that has been resected or excised due to tumor or trauma/fracture. The device is intended for use as a vertebral body replacement in the thoracolumbar spine (from T1 to L5) The Lanx Vertebral Body Replacement System may also be used in the thoracolumbar spine (i.e., T1- L5) for partial replacement (i.e., partial vertebrectomy) of a diseased vertebral body resected or excised for the treatment of tumors in order to achieve anterior decompression of the spinal cord and neural tissues, and to restore the height of a collapsed vertebral body. The Lanx Vertebral Body Replacement System

is also indicated for treating fractures of the thoracic and lumbar spine. The Lanx Vertebral Body Replacement System is designed to restore the biomechanical integrity of the anterior, middle, and posterior spinal column. For either indication the system must be used with supplemental internal fixation. Supplemental internal fixation is required to properly utilize this system.

Performance Data

Performance was established via mechanical testing that included static and dynamic compression and static and dynamic torsion per ASTM F2077 and subsidence testing per ASTM F2267. In all instances, the Lanx Fusion System met the established acceptance criteria and performed as intended.

Substantial Equivalence

The Lanx Fusion System is as safe and effective as the predicate Lanx Fusion System (K083815), LDR Spine MC+ Cervical Interbody Fusion System (K091088), and the Spinal Elements Crystal Cervical Cage System (K073351).

The additional cervical intervertebral body fusion device implants included in the product line extension have the same intended use, indications, technological characteristics, and principles of operation as the cervical intervertebral body fusion device implants of the previously-cleared Lanx Fusion System (K083815). Performance data demonstrate that these additions to the Lanx Fusion System do not raise new issues related to safety or efficacy; hence the modified system is as safe and effective as the predicate devices. Thus, the modified device is substantially equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Lanx, Inc.
% Mr. William Sandul
390 Interlocken Crescent, Suite 890
Broomfield, Colorado 80021

Re: K103660
Trade/Device Name: Lanx Fusion System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: ODP, MQP
Dated: February 15, 2011
Received: February 17, 2011

FEB 2 8 2011

Dear Mr. Sandul:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

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 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/MedicalDevices/Safety/ReportaProblem/default.htm 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/MedicalDevices/ResourcesforYou/Industry/default.htm.

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): K103660

Device Name: Lanx Fusion System

Indications for Use:

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When used as a lumbar intervertebral body fusion device, the Lanx Intervertebral Body/VBR Fusion System ("Lanx Fusion System") is intended for spinal fusion procedures to be used with autogenous bone graft in skeletally mature patients with degenerative disc disease ("DDD") at one or two contiguous spinal levels from L2-S1. DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. These patients should have had six months of non-operative treatment. These DDD patients may have had a previous non-fusion spinal surgery at the involved spinal level(s), and may have up to Grade 1 spondylolisthesis or retrolisthesis at the involved level(s). The Lanx Fusion System is to be implanted via an anterior or posterior approach and is to be combined with supplemental fixation. Approved supplemental fixation systems include the Lanx Spinal Fixation System.

When used as vertebral body replacement, the Lanx Intervertebral Body/VBR Fusion System ("Lanx Fusion System") is indicated for use to replace a vertebral body that has been resected or excised due to tumor or trauma/fracture. The device is intended for use as a vertebral body replacement in the thoracolumbar spine (from T1 to L5) The Lanx Vertebral Body Replacement System may also be used in the thoracolumbar spine (i.e., T1- L5) for partial replacement (i.e., partial vertebrectomy) of a diseased vertebral body resected or excised for the treatment of tumors in order to achieve anterior decompression of the spinal cord and neural tissues, and to restore the height of a collapsed vertebral body. The Lanx Vertebral Body Replacement System is also indicated for treating fractures of the thoracic and lumbar spine. The Lanx Vertebral Body Replacement System is designed to restore the biomechanical integrity of the anterior, middle, and posterior spinal column. For either indication the system must be used with supplemental internal fixation. Supplemental internal fixation is required to properly utilize this system.

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number K103660