510(k) SUMMARY

MAR 1 8 2013

Lanx, Inc's Intervertebral Body/VBR Fusion System

Submitter's Information

Name and Address:	Lanx, Inc. 310 Interlocken Parkway, Suite 120 Broomfield, CO 80021 (303) 443-7500
Contact Person:	Alan Burkholder
Date Prepared:	March 12, 2013

Device Identification

Proprietary Name:	Lanx Lateral-SA System
Common Name:	Vertebral Body Replacement/Intervertebral Body Fusion Device with Integrated Fixation, Lumbar
Classification:	Orthosis, spinal intervertebral fusion and/or Spinal intervertebral body fixation orthosis (per 21 CFR § 888.3080 and/or § 888.3060) (OVD, MAX, MQP, ODP)

Predicate Device Information

K102738 Lanx SA System

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 combined with supplemental fixation (except as noted below). Approved supplemental fixation systems include the Lanx Spinal Fixation System. The Lanx SA standalone interbody implants, when implanted via an anterior approach and used with the integrated fixation screws, do not require use of supplemental fixation. The Lanx Lateral-SA implants are to be used with supplemental fixation.

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.

Device Description & Technological Characteristics

The purpose of this 510(k) submission is to include additional PEEK spacer and titanium screw fixation configurations to the Lanx SA System. The new Lanx Lateral-SA system has the same intended use, principles of operation, and technological characteristics as the current Lanx SA system.

The Lanx Lateral-SA System devices are made of PEEK (OPTIMA®) per ASTM F2026 and/or Titanium alloy (Ti-6Al-4V ELI) per ASTM F136. The PEEK components include Tantalum markers per ASTM F560. The Fusion System has a hollowed out area to accommodate bone graft, and transverse grooves to improve fixation and stability. Additional fixation and stability is provided by screws which are made from an implant grade titanium alloy (Ti-6Al-4V ELI) meeting the requirements of ASTM F136. It is available in a variety of different sizes to accommodate anatomical variation in different vertebral levels and/or patient anatomy. The Lanx Lateral-SA System is provided non-sterile.

Performance Data

Performance testing and engineering analysis was performed to demonstrate substantial equivalence to the predicate device. Performance testing included tests per ASTM F2077 (static and dynamic compression, static torsion), ASTM F2267 (subsidence) and ASTM F1877 (wear debris). In all instances, the modified device met or exceeded predicate device performance,

functioned as intended and therefore demonstrated substantial equivalence to the predicate device.

Substantial Equivalence

The Lanx Lateral-SA system implants included in the product line extension have the same intended use, technological characteristics, and principles of operation as the previously cleared Lanx SA devices (K102738). The minor differences in the new components do not raise any new issues of safety or effectiveness. Performance data presented also demonstrated comparable properties to the previously cleared Lanx SA system devices. Thus, the modified device has been shown to be substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

March 18, 2013

Lanx, Incorporated
% Mr. Alan Burkholder
Director of Engineering
310 Interlocken Parkway, Suite 120
Broomfield, Colorado 80021

Re: K123767
Trade/Device Name: Lanx Lateral-SA System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: OVD, MAX, MQP, ODP
Dated: February 8, 2013
Received: February 7, 2013

Dear Mr. Burkholder:

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,

Erin D Keith

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

Enclosure

Indications for Use Statement

510(k) Number (if known): K123767

Device Name: Lanx Lateral-SA System

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 combined with supplemental fixation (except as noted below). Approved supplemental fixation systems include the Lanx Spinal Fixation System. The Lanx SA standalone interbody implants, when implanted via an anterior approach and used with the integrated fixation screws, do not require use of supplemental fixation. The Lanx Lateral-SA implants are to be used with supplemental fixation.

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Stephanie Bechtold -S

(Division Sign-Off)
Division of Orthopedic Devices
510(k) Number: K123767