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510(k) SUMMARY

Lanx's Small Intervertebral Body/VBR Fusion Device

OCT 21 2008

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

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

Phone: 303-443-7500
Facsimile: 303-443-7501

Contact Person: Alan Burkholder

Date Prepared: October 17, 2008

Name of Device and Name/Address of Sponsor

Lanx Small Intervertebral Body/VBR Fusion Device

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

Common or Usual Name

Intervertebral Body Fusion Device

Classification Name

Orthosis, spinal intervertebral fusion

Predicate Devices

Globus Medical, Inc.'s Patriot Spacers: Colonial ACDF
Spinal Elements, Inc.'s Crystal
SpineSmith Partners L.P.'s Cimplicity Spinal System

Intended Use / Indications for Use

When used as a cervical intervertebral body fusion device, the Lanx Small Intervertebral Body/VBR 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 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 Small Intervertebral Body/VBR 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 Small Intervertebral Body/VBR 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.

Technological Characteristics

The Lanx Small Intervertebral Body/VBR Fusion system is made of PEEK-OPTIMA® or titanium alloy. The Fusion System has a hollowed out area to accommodate autogenous bone graft, and transverse grooves to improve fixation and stability. It is available in a variety of different sizes to accommodate anatomical variation in different vertebral levels and/or patient anatomy. The Lanx Small Intervertebral Body/VBR Fusion System is provided non-sterile.

Performance Data

Performance testing was conducted per ASTM F2077-03 and ASTM F2267-04. In all instances, the Lanx Small Intervertebral Body/VBR Fusion System met acceptance criteria and functioned as intended.

Substantial Equivalence

The Lanx Small Intervertebral Body/VBR Fusion Device is as safe and effective as the Globus Medical, Inc. Patriot Spacers: Colonial ACDF, the Spinal Elements, Inc. Crystal, and the SpineSmith Partners L.P. Cimplicity Spinal System.

The Lanx Small Intervertebral Body/VBR Fusion Device has the same intended uses and similar indications, technological characteristics, and principles of operation as its predicate devices. The minor technological differences between the Lanx Small Intervertebral Body/VBR Fusion Device and its predicate devices raise no new issues of safety or effectiveness. Performance data demonstrate that the Lanx Small Intervertebral Body/VBR Fusion Device is as safe and effective as the predicate devices. Thus, the Lanx Small Intervertebral Body/VBR Fusion Device is substantially equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 21 2008

Lanx, LLC
% Mr. Alan Burkholder
Senior Project Engineer
390 Interlocken Crescent, Suite 890
Broomfield, Colorado 80021

Re: K082774
Trade Name: Lanx Small Intervertebral Body/VBR Fusion Device
Regulation Number(s): 21 CFR 888.3080
Regulation Names: Intervertebral body fusion device.
Regulatory Class: Class II
Product Code: ODP, MAX, MQP
Dated: September 18, 2008
Received: September 22, 2008

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.

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 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 Statement

510(k) Number (if known): K082774

Device Name: Lanx Small Intervertebral Body/VBR Fusion Device

Indications for Use:

When used as a cervical intervertebral body fusion device, the Lanx Small Intervertebral Body/VBR 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 Small Intervertebral Body/VBR 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 Small Intervertebral Body/VBR 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)

(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 K082774