

FEB 10 2011

**510(k) SUMMARY**

**Lanx, Inc's 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

Contact Person: Alan Burkholder

Phone: 303-501-8411

Facsimile: 303-443-7501

Date Prepared: September 21, 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**

Vertebral Body Replacement/Intervertebral Body Fusion Device

**Classification Name**

21 CFR 888.3080, Orthosis, spinal intervertebral fusion

21 CFR § 888.3060, Spinal intervertebral body fixation orthosis

**Predicate Devices**

Lanx Fusion System (K083815)

Synthes SynFix-LR (K072253)

### **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 (except as noted below). Approved supplemental fixation systems include the Lanx Spinal Fixation System. The Lanx SA standalone interbody implants, when used with the integrated fixation screws, do not require use of 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.

### **Technological Characteristics**

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 the Lanx SA standalone implant models with titanium components for additional fixation.

All devices in the Lanx Fusion System are made of PEEK (OPTIMA<sup>®</sup>) 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 Fusion System is provided non-sterile.

The additional models added to the product line have the same or similar intended use and indications, principles of operation and technological characteristics as the current Lanx Fusion System. The addition of titanium components for additional fixation, and indications for standalone lumbar interbody use, do not raise any new questions of safety or effectiveness. Mechanical testing and engineering analysis demonstrated comparable mechanical properties to the predicate devices.

### **Performance Data**

Performance testing for comparison of mechanical performance included tests per ASTM F2077 (static and dynamic compression, static torsion) and ASTM F2267 (subsidence). In all instances, the Lanx Fusion System met acceptance criteria and functioned as intended.

### **Substantial Equivalence**

The standalone implants included in the product line extension have the same or similar intended uses, indications, technological characteristics, and principles of operation as the previously cleared Lanx Intervertebral Body Fusion Device (K083815). Performance data demonstrate that these additions to the Lanx Fusion System do not raise new issues of safety or effectiveness; hence it is as safe and effective as the predicate devices. Thus, the modified device is substantially equivalent.



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

Lanx, Inc.  
% Mr. Alan Burkholder  
390 Interlocken Crescent, Suite 890  
Broomfield, Colorado 80021

SEP 12 2011

Re: K102738  
Trade/Device Name: Lanx Fusion 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 2, 2011  
Received: February 3, 2011

Dear Mr. Burkholder:

This letter corrects our substantially equivalent letter of February 10, 2011.

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 (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 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): K102738

Device Name: Lanx Fusion 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 implanted via an anterior or posterior approach and 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 used with the integrated fixation screws, do not require use of supplemental fixation.

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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 OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number K102738

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