# 510(k) SUMMARY

## Lanx Fusion System - Lateral

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

MAR 2 3 2011

Lanx, Inc.
390 Interlocken Crescent, Suite 890
Broomfield, CO 80021
Phone: 303-443-7500
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Contact Person: Alan Burkholder.

Date Prepared: February 25, 2011

**Name of Device and Name/Address of Sponsor**

Lanx Fusion System – Lateral (Lanx Lateral)

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

**Common or Usual Name**

Vertebral Body Replacement/Intervertebral Body Fusion Device

**Classification Name/Regulation Number**

21 CFR § 888.3080, Orthosis, spinal intervertebral fusion

**Predicate Devices**

Lanx, Inc: Lanx Intervertebral Body/VBR Fusion Device. (K083815)
Nuvasive: CoRoent (K071795, K052210)

**Intended Use / Indications for Use**

*When used as a lumbar intervertebral body fusion device, the Lanx Fusion System - Lateral ("Lanx Lateral") 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 Lateral 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 Fusion System - Lateral ("Lanx Lateral") 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 Lateral 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 Lateral is also indicated for treating fractures of the thoracic and lumbar spine. The Lanx Lateral 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 the Lanx Fusion System – Lateral ("Lanx Lateral"). The product line includes the Lanx Lateral implant models which include the addition of new footprints and configurations.

All devices in the Lanx Lateral are made of PEEK (OPTIMA®) per ASTM F2026. The PEEK components include Tantalum markers per ASTM F560. The Lanx Lateral 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 Lateral is provided non-sterile.

The devices in this product line have the same or similar intended use and indications, principles of operation, and technological characteristics as the current Lanx Fusion System. The minor difference between the predicate devices and the devices in this product line do not raise any new questions of safety or effectiveness. Mechanical testing and engineering analysis demonstrated comparable mechanical properties to the predicate device.

**Performance Data**

Performance testing was conducted per ASTM F2077 and ASTM Draft Z8423Z. In all instances, the Lanx Lateral met acceptance criteria and functioned as intended.

**Substantial Equivalence**

The devices included in this product line have the same or similar intended uses, indications, technological characteristics, and principles of operation as previously cleared Lanx Intervertebral Body/VBR Fusion Device (K083815). Performance data demonstrate that these devices do not raise new issues of safety or effectiveness; hence it is as safe and effective as its predicate devices. Thus, the devices are 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. Alan Burkholder
390 Interlocken Crescent, Suite 890
Broomfield, Colorado 80021

MAR 2 3 2011

Re: K103666
Trade/Device Name: Lanx Fusion System - Lateral
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: MAX, MQP
Dated: March 01, 2011
Received: March 02, 2011

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,

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): K103666

Device Name: Lanx Fusion System - Lateral

Indications for Use:

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

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Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number K103666