510(k) SUMMARY

Lanx Facet Screw System

Name of Firm and Contact

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

Date Prepared: May 13, 2010

Name of Device

Lanx Facet Screw System

Common or Usual Name

Facet Screw System

Classification

Unclassified, Product Code - MRW

Predicate Device

NuVasive Facet Screw (K020411, K001323)

Globus Corridor Fixation System (K083442)

Intended Use / Indications for Use

The Lanx Facet Screw System is intended to stabilize the spine as an aid to fusion through bilateral immobilization of the facet joints, with or without bone graft, at single or multiple levels, from C2 to S1 for 3.5mm and 4.0mm screws and from L1 to S1 for 4.5mm screws. For transfacet fixation, the screws are inserted posteriorly through the superior side of the facet, across the facet joint, and into the pedicle. For translaminar facet fixation, the screws are inserted posteriorly through the lateral aspect of the spinous process, through the lamina, through the superior side of the facet, across the facet joint, and into the pedicle. The Lanx Facet Screw System is indicated for treatment of any or all of the following:

- pseudoarthrosis and failed previous fusions which are symptomatic or which may cause secondary instability or deformity;

- spondylolisthesis;
- spondylolysis;
- degenerative disc disease (DDD) as defined by neck and/or back pain of discogenic origin as confirmed by radiographic studies;
- degeneration of the facets with instability and;
- trauma including spinal fractures and/or dislocations.

Device Description

The Lanx Facet Screw System consists of various screws and washers designed to compact juxtaposed facet articular processes to enhance spinal fusion and stability. The screws are available partially threaded or fully threaded, cannulated or non-cannulated, and in various diameters and lengths to accommodate patient anatomy. Lanx Facet Screw System implants are fabricated from medical grade titanium alloy (per ASTM F-136).

Performance Data

Performance testing and engineering analysis were conducted to characterize the performance of the Lanx Facet Screw System. Testing performed included dynamic and static three-point bend per ASTM F1264-03, cantilever bend per ASTM F2193, torsion and axial pull-out testing per ASTM F543. The device functioned as intended and the observed test results demonstrate substantial equivalence to the predicate devices.

Substantial Equivalence

The Lanx Facet Screw System has the same or similar intended use, indications, principles of operation, and technological characteristics as the predicate systems. Equivalency of this device is based on similarities in intended use, materials and design. Mechanical testing and engineering analysis demonstrated comparable mechanical properties to the predicate devices. Thus, the Lanx Facet Screw System is substantially equivalent to the predicate devices.

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. Michael Funk
Director of Engineering, Lumbar
390 Interlocken Crescent, Suite 890
Broomfield, Colorado 80021

AUG 16 2010

Re: K101364
Trade/Device Name: Lanx Facet Screw System
Regulatory Class: Unclassified
Product Code: MRW
Dated: May 13, 2010
Received: May 19, 2010

Dear Mr. Funk:

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 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

AUG 1 6 2010

Indications for Use Statement

510(k) Number (if known): K101364

Device Name: Lanx Facet Screw System

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)

(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 K101364