510(k) SUMMARY K131156

Lanx, Inc's Spinal Fixation System

MAY 2 4 2013

Submitter Information

Name and Address:	Lanx, Inc. 310 Interlocken Parkway, Suite 120 Broomfield, CO 80021 (303) 443-7500
Contact Person:	Michael Medina
Date Prepared:	May 23, 2013

Device Identification

Proprietary Name:	Lanx Spinal Fixation System
Common Name:	Spinal Fixation System
Classification:	Pedicle Screw Spinal System and/or Spinal Interlaminal Fixation Orthosis (per 21 CFR 888.3050 and/or 888.3070)
Product Code:	KWP

Predicate Device Information

K121316 Lanx Spinal Fixation System

Intended Use / Indications for Use

The Lanx Spinal Fixation System (SFS) is intended to be used to help provide immobilization and stabilization of spinal segments as an adjunct to fusion of the thoracic, lumbar and/or sacral spine. The System is intended for use with autograft or allograft.

The Lanx Spinal Fixation System is intended for posterior, non-cervical (T1-S2/ilium) pedicle and non-pedicle spinal fixation, to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following instabilities or deformities: degenerative disc disease (DDD, defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies); spondylolisthesis; trauma (i.e. fracture or dislocation); spinal stenosis; deformities or curvatures (i.e. scoliosis, kyphosis and/or lordosis); tumor; pseudoarthrosis; and failed previous fusion.

The Lanx Spinous Process Fusion Plate (SPFP) is a posterior, non-pedicle supplemental fixation device, intended for use at a single level in the non-cervical spine (T1-S1). It is intended for plate fixation/attachment to spinous processes for the purpose of achieving supplemental fusion in the following conditions: degenerative disc disease (defined as back pain of discogenic origin with

degeneration of the disc confirmed by history and radiographic studies); spondylolisthesis; trauma (i.e., fracture or dislocation); and/or tumor. The Lanx SPFP is intended for use with bone graft material, not intended for stand-alone use.

Device Description & Technological Characteristics

The purpose of this 510(k) submission is to modify the Surgical Technique for the Lanx Spinal Fixation System. No other changes have been made to the previously cleared system.

The Lanx Spinal Fixation System consists of various screws, hooks, rods, plates, connectors, etc. that are used to build a construct to provide supplemental stabilization of spinal segments to support fusion. The system components can be assembled in a variety of configurations, allowing the surgeon to tailor the construct to the particular needs of the patient.

The Lanx Spinal Fixation System implants are fabricated from medical grade titanium, titanium alloy and/or cobalt chrome alloy per ASTM F67, ASTM F1580, ASTM F136 and ASTM F1537. Titanium and cobalt chrome components may be used together within the same construct. These components should never be used with stainless steel implant components.

Performance Data

No performance data was submitted to determine substantial equivalence.

Substantial Equivalence

The Lanx Spinal Fixation System has the same intended use and indications for use, and the same or very similar technological characteristics and principles of operation as the predicate system. Thus, the Lanx Spinal Fixation System is 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 20993-002

May 24, 2013

Lanx, Incorporated
% Mr. Michael Medina
Manger, Regulatory Affairs
310 Interlocken Parkway, Suite 120
Broomfield, Colorado 80021

Re: K131156
Trade/Device Name: Lanx Spinal Fixation System
Regulation Number: 21 CFR 888.3050
Regulation Name: Spinal interlaminal fixation orthosis
Regulatory Class: II
Product Code: KWP
Dated: April 19, 2013
Received: April 24, 2013

Dear Mr. Medina:

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 contact 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. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

For 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): K131156

Device Name: Lanx Spinal Fusion System

Indications for Use:

The Lanx Spinal Fixation System (SFS) is intended to be used to help provide immobilization and stabilization of spinal segments as an adjunct to fusion of the thoracic, lumbar and/or sacral spine. The System is intended for use with autograft or allograft.

The Lanx Spinal Fixation System is intended for posterior, non-cervical (T1-S2/ilium) pedicle and non-pedicle spinal fixation, to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following instabilities or deformities: degenerative disc disease (DDD, defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies); spondylolisthesis; trauma (i.e. fracture or dislocation); spinal stenosis; deformities or curvatures (i.e. scoliosis, kyphosis and/or lordosis); tumor; pseudoarthrosis; and failed previous fusion.

The Lanx Spinous Process Fusion Plate (SPFP) is a posterior, non-pedicle supplemental fixation device, intended for use at a single level in the non-cervical spine (T1-S1). It is intended for plate fixation/attachment to spinous processes for the purpose of achieving supplemental fusion in the following conditions: degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies); spondylolisthesis; trauma (i.e., fracture or dislocation); and/or tumor. The Lanx SPFP is intended for use with bone graft material, not intended for stand-alone use.

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 IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Amy S. Graf -S

(for Ronald Jean)

(Division Sign-Off)
Division of Orthopedic Devices
510(k) Number: K131156