APR - 7 2010

510(k) SUMMARY

Lanx Anterior Plating 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: April 6, 2010

Name of Device

Lanx Anterior Plating System

Common or Usual Name

Spinal Fixation System

Classification

KWQ – 21 CFR 888.3060, Spinal Intervertebral Body Fixation Orthosis

Predicate Device

Medtronic Sofamor Danek Z-Plate (K922543, K982875)

Blackstone Medical Unity (K043548, K061229)

Synthes ATB (K022791)

Intended Use / Indications for Use

The Lanx Anterior Plating System is intended to provide fixation of the thoracic, lumbar and/or sacral spine (T1-S1) as an adjunct to fusion using autograft or allograft in skeletally mature patients 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);
- Spinal stenosis (indicated for L1- S1 only);

- Spondylolisthesis;
- Deformities or curvatures (i.e., scoliosis, kyphosis and/or lordosis);
- Trauma (i.e., fracture, dislocation, or subluxation);
- Spondylolysis;
- Tumor;
- Pseudoarthrosis; and/or
- Failed previous fusion.

The Lanx Anterior Plating System is indicated for use via the lateral or anterolateral surgical approach for fixation of the thoracic and thoracolumbar spine, or via the anterior surgical approach for fixation of the lumbosacral spine below the bifurcation of the great vessels.

Device Description

The Lanx Anterior Plating System consists of various plates and screws 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.

Performance Data

Performance testing and engineering analysis were conducted to characterize the performance of the Lanx Anterior Plating System. The subject device was evaluated under ASTM F1717 construct testing for static axial compression, static torsion and dynamic axial compression testing versus a predicate device. The device functioned as intended and the observed test results demonstrate substantial equivalence to the predicate devices.

Substantial Equivalence

The Lanx Anterior Plating 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 Anterior Plating 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 W-O66-0609
Silver Spring, MD 20993-0002

APR - 7 2010

Lanx, Inc.
% Mr. Michael Funk
390 Interlocken Crescent, Suite 890
Broomfield, Colorado 80021

Re: K092765
Trade/Device Name: Lanx Anterior Plating System
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal intervertebral body fixation orthosis
Regulatory Class: Class II
Product Code: KWQ
Dated: March 19, 2010
Received: March 23, 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, labcling, 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: K092765

Device Name: Lanx Anterior Plating 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 K092765