K071877

SEP 17 2007

510(k) SUMMARY

Lanx LLC's Spinal Fixation System

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

Lanx, LLC
390 Interlocken Crescent, Suite 890
Broomfield, CO 80021
303-443-7500

Contact Person: Andrew Lamborne

Date Prepared: July 5, 2007

Name of Device and Name/Address of Sponsor

Lanx Spinal Fixation System

Lanx, LLC
390 Interlocken Crescent, Suite 890
Broomfield, CO 80021

Common or Usual Name

Spinal Fixation System

Classification

Class II, Pedicle Screw Spinal System (MNI) and/or Spinal Interlaminal Fixation Orthosis (KWP)
21 C.F.R. § 888.3070 and/or 21 C.F.R. § 888.3050

Predicate Devices

Lanx Spinal Fixation System (K043484)
Medtronic Sofamor Danek CD Horizon Spinal System (K043053)

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 Lanx SFS is intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar and sacral spine: severe spondylolisthesis (grades 3 and 4) of the L5-S1 vertebra; degenerative spondylolisthesis with objective evidence of neurologic impairment; fracture; dislocation; scoliosis; kyphosis; spinal tumor; and failed previous fusion (pseudarthrosis).

The Lanx Spinous Process Fusion Plate (SPFP) is a posterior, non-pedicle supplemental fixation device, intended for use 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 and is not intended for stand-alone use.

Technological Characteristics

The Lanx Spinal Fixation System consists of various screws, 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 purpose of this 510(k) is to add the Spinous Process Fusion Plate to the Lanx SFS.

Performance Data

Performance testing was performed and submitted to characterize the new components being added to the system. The Lanx Spinal Fixation System functioned as intended and the observed test results demonstrate substantial equivalence to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Lanx, LLC
% Hogan & Hartson L.L.P.
Attn: Janice M. Hogan, Esq.
1835 Market Street, 28th Floor
Philadelphia, Pennsylvania 19102

SEP 17 2007

Re: K071877
Trade/Device Name: Lanx Spinal Fixation System
Regulation Number: 21 CRF 888.3050
Regulation Name: Spinal interlaminal fixation orthosis
Regulatory Class: Class II
Product Code: MNI, KWP
Dated: July 5, 2007
Received: July 10, 2007

Dear Ms. Hogan:

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 such 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276--0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

cc: HFZ-401 DMC
HFZ-404 510(k) Staff
HFZ- Division
D.O.

OC Numbers:

Division of Enforcement A	240-276-0115
Dental, ENT and Ophthalmic Devices Branch	240-276-0115
OB/GYN, Gastro. & Urology Devices Branch	240-276-0115
General Hospital Devices Branch	240-276-0115
General Surgery Devices Branch	240-276-0115
Division of Enforcement B	240-276-0120
Cardiovascular & Neurological Devices Branch	240-276-0120
Orthopedic, Physical Medicine & Anesthesiology Devices and Radiological Devices	240-276-0120

Last Updated: Brandi Stuart – 7/9/07

Indications for Use Statement

510(k) Number (if known): K071877

Device Name: Lanx Spinal Fixation System

Indications for Use:

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Prescription Use __X___	AND/OR	Over-The-Counter Use____
(Part 21 C.F.R. 801 Subpart D)		(21 C.F.R. 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE -- CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, [illegible]
and Neurological [illegible]

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