MAY 16 2005 K043484

510(k) Summary Information *Premarket Notification, Section 510(k)*	*LANX, LLC.* *MAY 11, 2005*

Regulatory Authority: Safe Medical Devices Act of 1990, 21 CFR 807.92

1. *Device Name:*

Trade Name: ***Lanx Spinal Fixation System***
Common Name(s): Posterior lumbar spine system
Classification Name(s): Pedicle Screw Spinal System (888.3070)

2. *Establishment Name & Registration Number:*

Name: LANX, LLC. **Number:** 3004485144

3. *Equivalent Predicate Device:*

LANX, LLC. believes that the ***Lanx Spinal Fixation System*** is substantially equivalent to the following:

- Orthopedic Alliance, LLC, K033826, Orthopedic Alliance Spine System

Equivalence can be seen in the design, material composition, surgical technique and intended use.

4. *Device Description:*

The Lanx Spinal Fixation System is a posterior attachment pedicle fixation system. The system is made up of a series of screws, rods, cross-links and interlocking mechanisms.

Materials: Titanium Alloy ASTM F136-92 ISO 5832-3
Testing Summary: Fatigue and static testing conducted in accordance with ASTM F-1717-01 are complete. The test results demonstrate that the device will perform in a manner substantially equivalent to available spinal fixation systems.

5. *Intended Use:*

The ***Lanx Spinal Fixation System*** 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).

6. *Applicant Name & Address:*

Lanx, LLC, 1155 Alpine Avenue, Suite 320, Boulder, CO 80304

7. *Company Contact:*

Michael Fulton, M.D., Lanx, LLC, 1155 Alpine Avenue, Suite 320, Boulder, CO 80304
Phone: 303-443-7500

8. *Submission Correspondent:*

Mr. David W. Schlerf, Buckman Company, Inc., 200 Gregory Lane, Suite C-100
Pleasant Hill, CA 94523-3389 Phone: 925.356.2640 – Fax:925.356.2654 david@fda-help.com

9. *Performance Standards:*

LANX, LLC. meets required general controls authorized under Sections 501, 502, 510, 516, 518, 519, and 520 of the Food, Drug, and Cosmetic Act.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 16 2005

Lanx, LLC
C/o Mr. David W. Schlerf, V.P.
Buckman Company Incorporated
200 Gregory Lane, Suite C-100
Pleasant Hill, California 94523-3389

Re: K043484
Trade/Device Name: Lanx Spinal Fixation System
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle Screw Spinal System
Regulatory Class: II
Product Code: MNI
Dated: March 21, 2005
Received: March 23, 2005

Dear Mr. Schlerf:

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 Office of Compliance at (240) 276-0120 . Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Miriam C. Provost, Ph.D.
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number: K043484

Device Name(s): ***Lanx Spinal Fixation System***

Indications for Use(s) of the Device:

The ***Lanx Spinal Fixation System*** 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).

Prescription Use ____X____ OR Over-The-Counter Use _____

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NECESSARY

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K043484

(Per 21 CFR 801.109) (Optional format 1-2-96)