K052384

OCT 7 - 2005

510(k) Summary Information *Premarket Notification, Section 510(k)*	*Lanx LLC* **SEPT 17, 2005**

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

1. *Device Name:*

Trade Name: ***Lanx VBR***
Common Name(s): Vertebral body replacement
Classification Name(s): Spinal intervertebral body fixation orthosis

2. *Establishment Name & Registration Number:*

Name: ***Lanx LLC***
Number: 3004485144

3. *Classification(s):*

Sec. 888.3060 Spinal intervertebral body fixation orthosis.

(a) ***Identification.*** A spinal intervertebral body fixation orthosis is a device intended to be implanted made of titanium. It consists of various vertebral plates that are punched into each of a series of vertebral bodies. An eye-type screw is inserted in a hole in the center of each of the plates. A braided cable is threaded through each eye-type screw. The cable is tightened with a tension device and it is fastened or crimped at each eye-type screw. The device is used to apply force to a series of vertebrae to correct "sway back," scoliosis (lateral curvature of the spine), or other conditions.

Device Class: Class II for the requested indications
Classification Panel: Orthopaedic and Rehabilitation Devices Panel
Product Code(s): MQP

4. *Equivalent Predicate Device:*

Lanx LLC believes that the ***Lanx VBR*** is substantially equivalent to the following:
1. K003709, Mesh Cage, Surgical Dynamics
2. K001340, Stackable Cage, DePuy
3. K040928, PEEK Cage, Interpore/Cross
4. K042268, EBI CAS Spine Spacer System, EBI. L.P.

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

5. *Device Description:*

Implants: The ***Lanx VBR*** implants consists of a series of flat, trapezoidal, rectangular and curved shaped implants. The device is offered in different size/configurations to better approximate the anatomical variation observed in different vertebral levels and/or patient anatomy. The devices are manufactured with a hollowed out central area to accommodate bone graft material. The upper and lower surfaces are manufactured in such a way that a series of transverse slots or grooves are formed to improve stability and fixation once the device is inserted.
Materials: all implants are made from implant grade PEEK with titanium position markers.
Instruments: The instruments are made from instrument grade stainless steel.

Indications for Use. The Lanx VBR System is indicated for use to replace a vertebral body that has been resected or excised due to tumor or trauma/fracture. The device is intended for use as a vertebral body replacement in the thoracolumbar spine (from T1 to L5) The Lanx VBR System may also be used in the thoracolumbar spine (i.e., Ti- L5) for partial replacement (i.e., partial vertebrectomy) of a diseased

vertebral body resected or excised for the treatment of tumors in order to achieve anterior decompression of the spinal cord and neural tissues, and to restore the height of a collapsed vertebral body. The Lanx VBR System is also indicated for treating fractures of the thoracic and lumbar spine. The Lanx VBR System is designed to restore the biomechanical integrity of the anterior, middle, and posterior spinal column. For either indication the system must be used with supplemental internal fixation. Supplemental internal fixation is required to properly utilize this system.

Testing Summary. Fatigue and static testing is complete. Samples were tested according to accepted engineering and scientific principals. Test results demonstrate that the system can be expected to perform in a manner equivalent to the comparison device. Additionally, a device material Master File (MAF) recorded with the FDA provided additional biocompatibility information.

6. *Applicant Name & Address:*

Lanx, LLC
1155 Alpine Avenue, Suite 320
Boulder, CO 80304
303-443-7500
Fax: 303-443-7501

7. *Company Contact:*

Michael Fulton, M.D.
Lanx, LLC
1155 Alpine Avenue, Suite 320
Boulder, CO 80304
303-443-7500
Fax: 303-443-7501

8. *Submission Correspondent:*

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

9. *Performance Standards:*

United States Food and Drug Administration mandated performance standards for this device do not exist. Various voluntary performance standards are utilized. Voluntary standards utilized include ASTM, Standard Operating Procedures, vendor & process certification and qualification procedures, Quality Systems Regulations, ISO materials standards and ISO 9000 series quality regulations. **LANX, LLC.** also meets appropriate general controls authorized under Sections 501, 502, 510, 516, 518, 519, and 520 of the Food, Drug, and Cosmetic Act.

10. *Sterilization Information:*

The ***Lanx Spinal Fixation System*** is supplied ***"NON-STERILE"*** and must be sterilized prior to use. The recommended sterilization process is high temperature steam autoclave sterilization. The referenced sterilization cycle produces a Sterility Assurance Level (SAL) of at least 10^{-6}.

The validated cycle is:

Method:	Steam
Cycle:	Gravity
Temperature:	270°F (134°C)
Exposure Time:	18 minutes

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 7 - 2005

Lanx, LLC
c/o David W. Schlerf
Buckman Company, Inc.
200 Gregory Lane, Suite C-100
Pleasant Hill, California 94523

Re: K052384
Trade/Device Name: Lanx VBR
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal intervertebral body fixation orthosis
Regulatory Class: II
Product Code: MQP
Dated: August 26, 2005
Received: August 30, 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,

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

Enclosure

510(k) Number: K052384

Device Name(s): ***LanxVBR***

Indications for Use:

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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 K052384

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