APR 2 5 2013

510(k) Summary for the Vault ALIF System

In accordance with 21 CFR 807.92 of the Federal Code of Regulations the following 510(k) summary is submitted for the Vault ALIF System

1. GENERAL INFORMATION

Date Prepared: February 18, 2013

Trade Name: Vault ALIF System

Common Name: Intervertebral Body Fusion Device

Classification Name: Intervertebral Fusion Device With Integrated Fixation, Lumbar

Class: II

Product Code: OVD

CFR section: 21 CFR section 888.3080

Device panel: Orthopedic

Legally Marketed Predicate Device: Spinal USA Vault ALIF System - K103369

Submitter: Spinal USA
2050 Executive Drive
Pearl, MS 39208
601-420-424

Contact J.D. Webb
1001 Oakwood Blvd
Round Rock, TX 78681
512-388-0199 Tele
512-692-3699 Fax
e-mail: jdwebb@orthomedix.net

2. DEVICE DESCRIPTION

The Vault ALIF System consists of implants with various widths, heights, lengths and bone screws to accommodate individual patient anatomy and autogenous bone graft size. All components are manufactured from medical grade polyetheretherketone (PEEK LT1).

Change from Predicate:

This Special 510(k) is submitted in order to gain clearance for the Redesigned Vault ALIF System.

Materials:

Optima LT1 PEEK (ASTM F2026)
Ti-6AL-4V (ASTM F136)

3. INTENDED USE

The Vault ALIF System is indicated for intervertebral body fusion of the spine in skeletally mature patients. The device system is designed for use with autograft to facilitate fusion. One device is used per intervertebral space.

The Vault ALIF System is intended for use at either one level or two contiguous levels in the lumbar spine, from L2 to S1, for the treatment of degenerative disc disease (DDD) with up to Grade I spondylolisthesis. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The lumbar device is to be used with autogenous bone graft. Patients should have at least six months of non-operative treatment prior to treatment with a lumbar intervertebral fusion device.

The Vault ALIF System is a stand-alone system intended to be used with the bone screws provided and requires no additional supplementary fixations.

4. SUMMARY OF TECHNOLOGICAL CHARACTERISTICS / SUBSTANTIAL EQUIVALENCE

The Spinal USA Vault ALIF System is substantially equivalent to the predicate device(s) in terms of intended use, design, mechanical safety and performances. The Spinal USA Vault ALIF System is manufactured from an equivalent material, is packaged and sterilized the using the same methods as the predicate device(s).

5. NON-CLINICAL TEST SUMMARY

The following tests were conducted:

- Dynamic axial compression per ASTM F2077
- Dynamic shear compression per ASTM F2077

The results of this testing indicate that the Redesigned Vault ALIF System is equivalent to predicate device.

6. CLINICAL TEST SUMMARY

No clinical studies were performed

7. CONCLUSIONS NONCLINICAL AND CLINICAL

Spinal USA considers the Redesigned Vault ALIF System to be equivalent to the predicate device listed above. This conclusion is based upon the device's similarities in principles of operation, technology, materials and indications for use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

Letter dated: April 25, 2013

Spinal USA
% The Orthomedix Group, Incorporated
Mr. J.D. Webb
1001 Oakwood Boulevard
Round Rock, Texas 78681

Re: K130445
Trade/Device Name: Vault ALIF System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: OVD
Dated: March 25, 2013
Received: March 27, 2013

Dear Mr. Webb

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" (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 -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): K130445

Device Name: Vault ALIF System

Indications for Use:

The Vault ALIF System is indicated for intervertebral body fusion of the spine in skeletally mature patients. The device system is designed for use with autograft to facilitate fusion. One device is used per intervertebral space.

The Vault ALIF System is intended for use at either one level or two contiguous levels in the lumbar spine, from L2 to S1, for the treatment of degenerative disc disease (DDD) with up to Grade I spondylolisthesis. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The lumbar device is to be used with autogenous bone graft. Patients should have at least six months of non-operative treatment prior to treatment with a lumbar intervertebral fusion device.

The Vault ALIF System is a stand-alone system intended to be used with the bone screws provided and requires no additional supplementary fixations.

Prescription Use X (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Anton E. Dmitriev, PhD
Division of Orthopedic Devices