510(k) Summary

Submitter Information: OsteoMed
3885 Arapaho Road
Addison, Texas 75001
Phone: (972) 677-4600
Fax: (972) 677-4601

NOV 29 2012

Contact Person: Mrs. Piedad Peña

Date Prepared: November 21, 2012

Device Information:

Proposed Trade Name: OsteoMed Spine PrimaLIF™ LLIF Unitary PEEK Lateral Lumbar Interbody Fusion System

Classification Name: Intervertebral body fusion device

Regulation Number: 21 CFR 888.3080

Device Product Code: MAX

Device Class: Class II

Predicate Devices:

Lanx Fusion System – Lateral (K103666)

Classification Name: Orthosis, spinal intervertebral fusion (21 CFR 888.3080 Product Code: MAX)

Device Class: II

DePuy Lumbar I/F Cage with VSP Spine System (P960025)

Classification Name: Intervertebral Fusion Device with Bone Graft, lumbar (21 CFR 888.3080 Product Code: MAX)

Device Class: II

Synthes Oracle Spacer (K072791)

Classification Name: Spinal Intervertebral Body Fusion (21 CFR 888.3080 Product Code: MAX)

Device Class: II

Device Description:

The **PrimaLIF™ LLIF Unitary PEEK Lateral Lumbar Interbody Fusion System** is a comprehensive interbody cage system that provides structural stability of the anterior column. It is comprised of unitary PEEK interbody cages of various sizes. The instruments provided with the system include osteoteomes, implant trials, and an inserter to facilitate placement of the interbody device.

Materials:

The device is made of PEEK (poly-ether-ether-ketone) manufactured from Invibio PEEK OPTIMA® LT1 as described by ASTM F 2026-08 with Tantalum markers inserted for visibility with imaging as described by ASTM F560-08.

The instrumentation is made from various grades of chrome coated stainless steel, anodized aluminum, and/or medical grade silicone.

Intended Use:

The **OSTEOMED PrimaLIF™ LLIF** is indicated for intervertebral body fusion of the lumbar spine to be used with autogenous bone graft, from L2 to S1, in skeletally mature patients who have had six months of non-operative treatment. The device is intended for use at either one level or two contiguous levels for the treatment of degenerative disc disease (DDD) and these patients may have up to Grade I spondylolisthesis or retrolisthesis at the involved levels. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The device is intended for use with supplemental fixation systems such as PrimaLOK™ SP and PrimaLOK™ FF which have been cleared for use in the lumbar spine.

The **PrimaLIF™ LLIF** implants are intended for single use only.

Technological Characteristics:

The predicate devices consist of interverterbal body fusion devices designed with wedge shaped noses, serrations or teeth at endplate contacting surfaces, and central cavities to hold bone graft along with instrumentation for facilitating placement of the device using a direct lateral approach. The OsteoMed **PrimaLIF™ LLIF** device also is designed with wedge shaped noses, serrations or teeth at endplate contacting surfaces, and central cavities to hold bone graft along with instrumentation for facilitating placement of the device using a direct lateral approach.

Material used for the **PrimaLIF™ LLIF** is the same as the Lanx Lateral and Synthes Oracle Spacer predicate devices, PEEK OPTIMA® LT1 as described by ASTM F 2026-08. This material is biocompatible.

Performance/Clinical Data:

The **PrimaLIF™ LLIF** device has been tested in static and dynamic axial compression per ASTM F2077 and static subsidence per ASTM F2267. The intended use of the device is the same as the predicate devices. Clinical testing is not required to support substantial equivalence.

In conclusion, the device is safe and effective and performs as well as the predicate devices.

OsteoMed
3885 Arapaho Road
Addison, Texas 75001
(973) 677-4600 FAX: (800) 390-2620
Customer Service: (800) 456-7779

Substantial Equivalence:

The basis of substantial equivalence for this device is based on similarities in intended use, anatomic location, mechanical properties and method of stabilization to the predicate devices including the Lanx Lateral (K103666), the DePuy Lumbar I/F Cage (P960025), and the Synthes Oracle Spacer (K072791), based on their promotional materials, labeling and FDA clearance letters. Also, the basis of substantial equivalence for this device is based on similarities in material of manufacture to the Lanx Lateral (K103666) and the Synthes Oracle Spacer (K072791) based on their promotional materials, labeling and FDA clearance letters.

Due to the similarity of materials and design to the predicate devices, OsteoMed believes that the **PrimaLIF™ LLIF** device does not raise any new safety or effectiveness issues and performs as well as the predicate devices.

OsteoMed
3885 Arapaho Road
Addison, Texas 75001
(974) 677-4600 FAX: (800) 390-2620
Customer Service: (800) 456-7779

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

November 29, 2012

OsteoMed LP
% Piedad Peña, M.S.
Manager, Regulatory Affairs
3885 Arapaho Road
Addison, Texas 75001

Re: K123207
Trade/Device Name: PrimaLIF™ LLIF Unitary PEEK Lateral Lumbar Interbody Fusion System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: MAX
Dated: October 11, 2012
Received: October 12, 2012

Dear Ms. Peña:

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 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,

Ronald P. Jean for

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): K123207

Device Name: PrimaLIF™ LLIF Unitary PEEK Lateral Lumbar Interbody Fusion System

Indications for Use:

The **PrimaLIF™ LLIF Unitary PEEK Lateral Lumbar Interbody Fusion System** (PrimaLIF™ LLIF) is indicated for intervertebral body fusion of the lumbar spine to be used with autogenous bone graft, from L2 to S1, in skeletally mature patients who have had six months of non-operative treatment. The device is intended for use at either one level or two contiguous levels for the treatment of degenerative disc disease (DDD) and these patients may have up to Grade I spondylolisthesis or retrolisthesis at the involved level(s). DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The device is intended for use with supplemental fixation systems such as PrimaLOK™ SP and PrimaLOK™ FF which have been cleared for use in the lumbar spine.

The **PrimaLIF™ LLIF** implants are intended for single use only.

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 IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Ronald P. Jean

(Division Sign-Off)
Division of Orthopedic Devices
510(k) Number: K123207