AUG 17 2010

510(k) Summary

Date:	20 May 2010
Sponsor:	OsteoMed Spine Inc* 3885 Arapaho Road Addison, TX 75001 Phone: (972) 677-4787 Fax: (972) 677-4778 * wholly owned subsidiary of OsteoMed LP
Contact Person:	Rebecca Ellis Vice President, RA/QA & Organizational Excellence
Proposed Trade Name:	PrimaLOK™$_{SP}$ Interspinous Fusion System
Device Classification	Class II
Classification Name:	Spinal interlaminal fixation orthosis
Regulation:	888.3050
Device Product Code:	KWP
Device Description:	The PrimaLOK™$_{SP}$ Interspinous Fusion System is a bilateral locking plate system which attaches to the spine at the spinous processes. It is available in various interspinous heights and widths to accommodate differing anatomic requirements.
Intended Use:	The PrimaLOK™$_{SP}$ Interspinous Fusion System 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 process 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 PrimaLOK™$_{SP}$ Interspinous Fusion System is intended for use at one level, with bone graft material and not intended for stand-alone use.
Materials:	The PrimaLOK™$_{SP}$ Interspinous Fusion System components are manufactured from titanium alloy (Ti-6Al-4V) as described by ASTM F136.
Predicate Devices:	CD Horizon® Spire Plate (Medtronic, K043053) Spinous Process Fusion [aka Aspen] Plate (Lanx, Inc., K071877)

Technological Characteristics:

The PrimaLOK$^{TM}_{SP}$ Interspinous Fusion System possesses the same technological characteristics as one or more of the predicates. These include:

- basic design: bilateral locking plate, having an interspinous cavity for bone graft that attaches to the spinous processes via spikes,
- material: titanium alloy,
- sizing: plate sizes are within the range of those in the predicate systems, and
- intended use: as described above

The PrimaLOK$^{TM}_{SP}$ Interspinous Fusion System possesses a modified technological characteristic in that it incorporates a polyaxial gripping feature. This feature permits full boney contact regardless of variations in spinous process morphometry. As the plate is tightened onto the spinous processes, the grips seat and lock. In this final, locked position, the spikes function exactly as the predicates.

Therefore the fundamental scientific technology of the PrimaLOK$^{TM}_{SP}$ Interspinous Fusion System is the same as previously cleared devices.

Performance Data:

Static compression, tension and torsion, and dynamic compression, and torsion of the worst case PrimaLOK$^{TM}_{SP}$ Interspinous Fusion System construct was performed according to a modified ASTM F1717 protocol. The mechanical results demonstrated that the PrimaLOK$^{TM}_{SP}$ Interspinous Fusion System performs as well as or better than the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

OsteoMed L.P.
% BackRoads Consulting, Inc.
Karen E. Warden, Ph.D.
Consultant
8202 Sherman Road
Chesterland, Ohio 44026-2141

AUG 17 2010

Re: K100354
Trade/Device Name: PrimaLOK™ SP Interspinous Fusion System
Regulation Number: 21 CFR 888.3050
Regulation Name: Spinal interlaminal fixation orthosis
Regulatory Class: Class II
Product Code: KWP
Dated: August 06, 2010
Received: August 09, 2010

Dear Dr. Warden:

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 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.

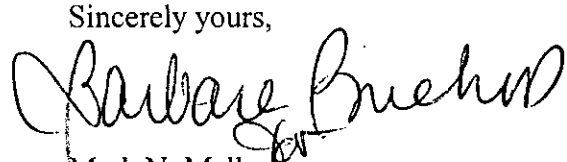
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

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,



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

Enclosure

K100354

Indications for Use Statement

510(k) Number: K100354

Device Name: **PrimaLOK™$_{SP}$ Interspinous Fusion System**

Indications for Use:

The PrimaLOK™$_{SP}$ Interspinous Fusion System 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 process 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 PrimaLOK™$_{SP}$ Interspinous Fusion System is intended for use at one level, with bone graft material and not intended for stand-alone use.

Prescription Use __X__ AND/OR Over-the-Counter Use_____

(21 CFR 801 Subpart D) (21 CFR 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 Surgical, Orthopedic,
and Restorative Devices

510(k) Number K100354