K053508

FEB 13 2006

510 (k) Summary

Name of Firm:	Synthes Spine 1302 Wrights Lane East West Chester, PA 19380
510 (k) Contact:	Angela Mikroulis, R.A.C. Regulatory Affairs Project Manager Phone: (610) 719-5718 Fax: (610) 719-5102
Trade Name:	SynFix™-LR
Date Prepared:	November 30, 2005
Common / Classification Name:	Spinal intervertebral body fixation orthosis
Device Product Code and Classification:	MQP 21 CFR 888.3060 Class II
Predicate:	K011037- Synthes Vertebral Spacer K050624- Stryker Spine AVS™ PL PEEK Spacer
Device Description:	The Synthes Synfix™-LR is a combination radiolucent and radiopaque vertebral body replacement device to provide structural stability in skeletally mature individuals following corpectomy. The Synfix™-LR may be used to accommodate the anatomical requirements of the space created by the corpectomy. Four screws are inserted through the anteriorly located plate into the neighboring vertebral bodies and lock securely to the plate using a tapered thread locking mechanism. The SynFix™-LR is intended to be used with Synthes supplemental internal fixation systems, e.g. ATLP, TSLP, VentroFix or USS. The interior of the spacer has openings that can be packed with bone (autograft or allograft). The Synfix™-LR is available as assembled components in various heights and geometrics to suit the individual pathology and anatomical conditions.
Intended Use/ Indications for Use:	The SynFix™-LR is a vertebral body replacement device intended for use in the thoracolumbar spine (T1-L5) to replace a collapsed, damaged, or unstable vertebral body resected or excised during partial and total vertebrectomy procedure due to tumor or trauma (i.e., fracture). The SynFix™-LR is intended to be used with Synthes supplemental internal fixation systems, e.g. ATLP, TSLP, VentroFix or USS. The interior of the spacer component of the SynFix™-LR can be packed with bone (autograft or allograft). SynFix™-LR is designed to provide anterior spinal column support even in the absence of fusion for a prolonged period.

Substantial Equivalence:	Documentation has been provided that demonstrates that the SynFix™-LR device is substantially equivalent (SE) to the previously cleared vertebral replacement device (K011037).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 13 2006

Angela Mikroulis, R.A.C.
Regulatory Affairs Project Manager
Synthes Spine Co. L.P.
1302 Wrights Lane East
West Chester, PA 19380

Re: K053508
Trade/Device Name: SynFix™-LR
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal intervertebral body fixation orthosis
Regulatory Class: Class II
Product Code: MQP
Dated: December 15, 2005
Received: December 16, 2005

Dear Ms. Mikroulis:

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,

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

Enclosure

Indications for Use Statement

510(k) Number (if known): K053508

Device Name: SynFix™-LR

Indications for Use:

The SynFix™-LR is a vertebral body replacement device intended for use in the thoracolumbar spine (T1-L5) to replace a collapsed, damaged, or unstable vertebral body resected or excised during partial and total vertebrectomy procedure due to tumor or trauma (i.e., fracture). The SynFix™-LR is intended to be used with Synthes supplemental internal fixation systems, e.g. ATLP, TSLP, VentroFix or USS. The interior of the spacer component of the SynFix™-LR can be packed with bone (autograft or allograft).

SynFix™-LR is designed to provide anterior spinal column support even in the absence of fusion for a prolonged period.

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Page __ of ___

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

510(k) Number K053508