

K062083

4.0 510 (k) Summary

APR - 3 2007

Name of Firm:	Synthes Spine 1302 Wrights Lane East West Chester, PA 19380
510 (k) Contact:	Bonnie Smith, RAC Synthes Spine Regulatory Affairs
Trade Name:	SynFix™-LR
Common / Classification Name:	Vertebral Body Replacement
Device Product Code and Classification:	MQP 21 CFR 888.3060 Class II
Predicates:	K011037 – Synthes Vertebral Spacer K010530 – Interpore Cross Geo™ Structure
Device Description:	<p>The Synthes Synfix™-LR is a combination radiolucent and radiopaque vertebral body replacement device that provides 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 adjacent vertebral bodies. The screws lock securely to the plate using a tapered- thread locking mechanism.</p> <p>The Synfix™-LR is available as assembled components in various heights and geometries to suit individual pathology and anatomical conditions.</p>
Intended Use/ Indications for Use:	<p>The SynFix-LR is a stand-alone vertebral body replacement device intended for use in the thoracolumbar spine (T1-L5) to replace a diseased vertebral body resected or excised during partial vertebrectomy procedures for the treatment of tumor or trauma (i.e. fracture) to achieve anterior decompression of the spinal cord and neural tissues. The interior of the spacer component of the SynFix-LR can be packed with bone (autograft or allograft).</p> <p>The SynFix-LR is designed to restore the biomechanical integrity of the anterior, middle, and posterior spinal column even in the absence of fusion for a prolonged period.</p>

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Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Synthes Spine
% Ms. Bonnie Smith
Senior Regulatory Affairs Specialist
1302 Wrights Lane East
West Chester, Pennsylvania 19380

APR - 3 2007

Re: K062083
Trade/Device Name: SynFix™ -LR Spacer
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal intervertebral body fixation orthosis
Regulatory Class: Class II
Product Code: MQP
Dated: February 1, 2007
Received: February 2, 2007

Dear Ms. Smith:

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
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K062083

5.0 Indications for Use Statement

Device Name: SynFix™-LR

Indications for Use:

The SynFix-LR is a stand-alone vertebral body replacement device intended for use in the thoracolumbar spine (T1-L5) to replace a diseased vertebral body resected or excised during partial vertebrectomy procedures for the treatment of tumor or trauma (i.e. fracture) to achieve anterior decompression of the spinal cord and neural tissues. The interior of the spacer component of the SynFix-LR can be packed with bone (autograft or allograft).

The SynFix-LR is designed to restore the biomechanical integrity of the anterior, middle, and posterior spinal column even in the absence of fusion for a prolonged period.

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 OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)



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

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