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5.0 510(K) Summary

AUG 1 8 2006

Name of Firm	Synthes Spine Co. L.P. 1302 Wrights Lane East West Chester, PA 19380
510(k) Contact	Bonnie J. Smith
Device Trade Name	Synex™ II
Common/Classification Name	Spinal intervertebral body fixation device
Panel/Product Code and Classification	Panel Code 87 Product Code MQP 21 CFR 888.3060: Class II
Predicate Device	K003836 - Synex™ Spacer
Device Description	The Synex II Spacer is a height expanding vertebral body replacement device consisting of a hollow central body and two endplates. The cylindrical body is comprised of two telescoping end pieces and a locking ring. The walls of the hollow cylindrical body have a plurality of holes intended for the placement of grafting materials to help achieve a solid fusion. Endplates are available in three footprint sizes. Each endplate is angled, has a plurality of holes and is designed with pyramidal teeth and small spikes to grip the adjacent vertebra.
Indications for Use	The Synex II Spacer is a vertebral body replacement device intended for use in the thoracolumbar spine (T1-L5) to replace a collapsed, damaged, or unstable vertebral body due to tumor or trauma (i.e., fracture). The Synex II device is intended to be used with Synthes supplemental internal fixation systems, e.g., TSLP, Pangea, or USS. The Synex II Spacer is designed to provide anterior spinal column support even in the absence of fusion for a prolonged period of time.

5.0 510(K) Summary (*continued*)

Substantial Equivalence	The Synthes Synex II Spacer implants are similar to the components of previously cleared spinal systems, Synthes Synex, K003836, and DePuy Stackable Cage System, K001340. The supplement fixation devices for use with the Synex II are cleared for use in patients with tumor, trauma or fractures.
Material	All components of the Synex II Spacer are manufactured from titanium alloy, Ti6Al7Nb (ASTM F 1295).
Performance Data	Mechanical testing in accordance with the "*Guidance for Spinal System 510(k)s*", issued May 3, 2004, was presented.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 18 2006

Synthes Spine Co. L.P.
% Ms. Bonnie J. Smith
Regulatory Affairs Project Manager
1302 Wrights Lane East
West Chester, Pennsylvania 19380

Re: K061891
Trade/Device Name: SYNEX™ II Spacer
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal Vertebral Body Replacement Device
Regulatory Class: Class II
Product Code: MQP
Dated: June 30, 2006
Received: July 3, 2006

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 (240) 276-3150 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

Indications For Use Statement

510(k) Number: K061891

Device Name: SYNEX™ II Spacer

The Synex™ II implant is a vertebral body replacement device intended for use in the thoracolumbar spine (T1-L5) to replace a collapsed, damaged, or unstable vertebral body due to tumor or trauma (i.e., fracture). The Synex II device is intended to be used with Synthes supplemental internal fixation systems, e.g., TSLP, Pangea and USS.

The Synex II device is designed to provide anterior spinal column support, even in the absence of fusion, for a prolonged period.

Prescription Use___X___ OR Over-the-Counter Use_____
(21 CFR 801.109 Subpart D) (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)

Barbara Buchman for MXM

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

510(k) Number K061891