K003836
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Synthes Spine 510(k) Premarket Notification
Synthes SynEx™ Spacer

Summary of Safety and Effectiveness Information MAY 2 9 2001

SPONSOR:

Synthes Spine Company, L. P.
1690 Russell Road
Paoli, PA 19301
(610) 647-9700
Contact: Jonathan Gilbert

DEVICE NAME:

Synthes Synex™ Spacer System

CLASSIFICATION:

Per CFR 21, §888.3060: Implant, fixation, spinal intervertebral body fixation orthosis devices. Class II.
Product code is MQP. The Panel code is 87.

PREDICATE DEVICE:

Depuy AcroMed Stackable Cage System - K001340 - K990148

DEVICE DESCRIPTION:

The SynEx device is a cylindrically-shaped titanium vertebral implant with a hollow core; the walls and endplates have a plurality of holes. Each implant consists of two telescoping end pieces and a locking ring. The plurality of holes and hollow core allow for the use of grafting materials to help achieve solid fusion. To resist expulsion, the implant endplates have teeth and small spikes to grip the endplates of the adjacent vertebrae.

The implant can be expanded vertically using the self-locking ratchet mechanism. A shoulder on the inner telescoping piece will not pass through the locking ring, preventing over-expansion of the implant.

The SynEx device is available in a variety of geometries and sizes. This enables the surgeon to choose the configuration suited to the individual pathology and anatomical condition. Only one SynEx device is to be implanted per spinal level. The interior of the spacer is open and can be packed with bone graft material.

The Synex Spacer implant is intended only for use with supplemental internal fixation. The supplemental internal fixation systems that may be used with the Synex™ Spacer implant include SYNTHES plate and rod systems (e.g., ATLP, VentroFix, USS).

INTENDED USE:

The SynEx™ 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™ Spacer is intended to be used with Synthes supplemental internal fixation systems, e.g., ATLP, VentroFix and USS. The interior of the spacer component of the SynEx™ Spacer System can be packed with bone.

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The SynEx™ Spacer is designed to provide anterior spinal column support even in the absence of fusion for a prolonged period.

MATERIAL: All components of the Synex™ Spacer are manufactured from titanium alloy Ti6Al7Nb (ASTM F1295) / ISO 5832-11.

PERFORMANCE DATA: Mechanical testing in accordance with the *"Guidance for Industry and FDA Staff, Guidance for Spinal System 510(k)s", September 27, 2000* was presented.

BASIS OF SUBSTANTIAL EQUIVALENCE: The Synthes Synex™ Spacer implants are similar to the components of previously cleared spinal systems (K990148 & K001340) with respect to certain technical characteristics. The supplemental fixation devices intended for use with the Synthes Synex™ Spacer are currently cleared for use in patients with either tumor, trauma or fractures.

Date revised: 2/21/01

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 2 9 2001

Mr. Jonathan Gilbert
Senior RA Associate
Synthes Spine
1690 Russell Road
Paoli, Pennsylvania 19301-1262

Re: K003836
Trade Name: SynEx™ Spacer
Product Code: MQP
Regulation: 888.3060
Class: II
Dated: March 7, 2001
Received: March 9, 2001

Dear Mr. Gilbert:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597, or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Synthes Spine 510(k) Premarket Notification
Synthes SynEx™ Spacer

Indications for Use Statement

510(k) Number (if known): K003836

Device Name: Synthes SynEx™ Spacer

INDICATIONS:

The SynEx™ 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™ Spacer is intended to be used with Synthes supplemental internal fixation systems, e.g., ATLP, VentroFix and USS. The interior of the spacer component of the SynEx™ Spacer System can be packed with bone.

The SynEx™ Spacer is designed to provide anterior spinal column support even in the absence of fusion for a prolonged period.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter Use___
(Per 21 CFR 801.109)

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

510(k) Number K003836