# Synthes Spine 510(k) Premarket Notification Vertebral Spacer

K011037



## 3.0 Summary of Safety and Effectiveness Information

SPONSOR:

Synthes (USA)
1690 Russell Road
Paoli, PA 19301
(610) 647-9700
Contact: Jonathan Gilbert

DEVICE NAME: Vertebral Spacer

CLASSIFICATION: The classification of the Vertebral Spacer components is Class II, as per the Code of Federal Regulations, Title 21, Section 888.3060: Implant, fixation, spinal intervertebral body fixation orthosis devices. The product code is MQP. The Panel code is 87.

PREDICATE DEVICE: DePuy-AcroMed Stackable Cage System - K001340

DEVICE DESCRIPTION: The Synthes Vertebral Spacer is a radiolucent vertebral body replacement device used in conjunction with supplemental internal fixation to provide structural stability in skeletally mature individuals following corpectomy.

The design of the Vertebral Spacer includes rectangular, stackable components of different cross-sectional sizes and height, bolts and a nut. The rectangular stackable components are available in four footprints and three heights to suit the individual pathology and anatomical conditions of the patient.

A Vertebral Spacer may be used individually, or two or more may be stacked together to accommodate the anatomical requirements of the vertebral space created by the corpectomy. When stacked, a bolt is inserted through the stackable components. A nut is then attached to the bolt to compress the stackable components together to create a rigid construct. The superior and inferior surfaces of the implants have ridges which engage between stacked implants and interface with the vertebral endplates.

The interior of the spacer is open and can be packed with bone graft. The implant is always implanted in the vertical position and the surgeon should select the largest footprint that will fill the void created by the tissue resection.

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| INTENDED USE: | The Vertebral 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 Vertebral 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 Vertebral Spacer system can be packed with bone.<br><br>The Vertebral Spacer is designed to provide anterior spinal column support even in the absence of fusion for a prolonged period. |
| MATERIAL: | Radiolucent polymer (PEEK) and titanium alloy (nut and bolt) materials in conformance with ASTM Standard Specifications. |
| PERFORMANCE DATA: | Mechanical and Chemical information were presented. |
| BASIS OF SUBSTANTIAL EQUIVALENCE: | The Synthes Vertebral Spacer implants are similar to the components of a previously cleared spinal system (K001340). The Vertebral Spacer material is comprised of polymer and contains no carbon fiber. The supplemental fixation devices intended for use with the Vertebral Spacer are currently cleared for patients with either tumor or fractures. |

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 1 2002

Mr. Jonathan Gilbert
Project Manager, Regulatory Affairs
Synthes (USA)
1690 Russell Road
Paoli, PA 19301

Re: K011037
Trade/Device Name: Vertebral Spacer
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal intervertebral body fixation orthosis
Regulatory Class: Class II
Product Code: MQP
Dated: April 19, 2002
Received: April 22, 2002

Dear Mr. Gilbert:

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 and additionally 21 CFR Part 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 Part 807.97). Other general information on your responsibilities under the Act may be obtained 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/dsma/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

## 2.0 Indications for Use Statement



510(k) Number (if known): ~~K[redacted]~~ K011037

Device Name: Vertebral Spacer

**Indications:**

The Vertebral 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 Vertebral 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 Vertebral Spacer system can be packed with bone.

The Vertebral 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)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

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

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

510(k) Number K011037