3.0 Summary of Safety and Effectiveness Information

MAR 1 7 2003

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

DEVICE NAME: Synthes Vertebral Spacer *Ti*

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: Vertebral body replacement device:
Synthes Vertebral Spacer, Ti: K020152
SE date: April 16, 2002.

DEVICE DESCRIPTION: The Vertebral Spacer Ti is a titanium vertebral body replacement device used in conjunction with supplemental internal fixation to provide structural stability in skeletally mature individuals following corpectomy or vertebrectomy and consists of:

- vertebral body replacement devices comprised of a variety of fixed heights and cross-sections.
- supplemental fixation currently cleared for use in treating patients for tumor, trauma or fractures of the vertebral body and
- manual surgical instrumentation used to prepare the anatomy and implant the Vertebral Spacer *Ti*.

There are no unique surgical instruments required for implantation of the submitted device system.

INTENDED USE: The Vertebral Spacer Ti 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 Ti* System is intended to be used with Synthes supplemental internal fixation systems, e.g., ATLP, VentroFix, USS and Small Stature USS. The interior of the spacer component of the Vertebral Spacer *Ti* can be packed with bone.

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

MATERIAL:	All components of the Vertebral Spacer Ti are manufactured from commercially pure titanium (ASTM F67) or titanium alloy Ti6Al7Nb (ASTM F1295).
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 Vertebral Spacer Ti implants are similar to the predicate Synthes Vertebral Spacer Ti body replacement device(s), (K020152) with respect to technical characteristics and performance. The supplemental fixation devices intended for use with the Vertebral Spacer Ti implants are currently cleared for use in patients with either tumor, trauma or fractures.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 17 2003

Mr. Jonathan Gilbert
RA Project Manager
Synthes Spine
Post Office Box 0548
1690 Russell Road
Paoli, Pennsylvania 19301

Re: K024364
Trade/Device Name: Synthes Vertebral Spacer Ti
Regulatory Number: 21, CFR 888.3060
Regulation Name: Spinal intervertebral body fixation orthosis
Regulatory Class: II
Product Code: MQP
Dated: December 30, 2002
Received: December 31, 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.

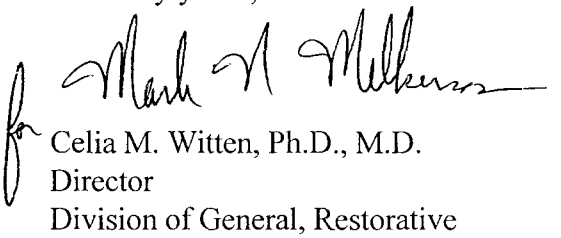
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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), 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" (21CFR 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,



for 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): K024364

Device Name: Synthes Vertebral Spacer Ti

Indications:

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

The Vertebral Spacer *Ti* 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 _____ OR Over-The-Counter Use____
(Per 21 CFR 801.109)

for Mark N Milhous

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

510(k) Number K024364