K080020

SYNTHES®
Spine

MAY 23 2008

5 510(k) Summary

510(k) Summary	
Name of Firm:	Synthes Spine 1302 Wrights Lane East West Chester, PA 19380
510(k) Contact:	Kirsten Stowell Associate Regulatory Affairs Specialist Telephone: 610-719-5534 Facsimile: 610-719-5102 Email: stowell.kirsten@synthes.com
Date Prepared:	January 2, 2008
Trade Name:	Synthes ArcoFix System
Classification:	21 CFR 888.3060 – Spinal Intervertebral Body Fixation Orthosis Class II Orthopaedic and Rehabilitation Devices Panel Product Code: KWQ
Predicates:	Synthes VentroFix MIS (K031100) Synthes Anterior Tension Band (ATB) System (K022791)
Device Description:	The Synthes ArcoFix System is an addition to Synthes' existing anterior/anterolateral/lateral thoracolumbar spine systems. The ArcoFix implant consists of an expandable plate and 4 bone screws, all manufactured from Titanium Aluminum Niobium (Ti-6Al-7Nb) ASTM F1295, the same as the predicates.
Intended Use/ Indications for Use:	Synthes ArcoFix System is indicated for use, via the lateral or anterolateral surgical approach, in the treatment of thoracic and thoracolumbar (T1-L5) spine instability as a result of the following: • Degenerative Disc Disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies) • Spondylolisthesis • Spondylolysis • Fracture (including dislocation and subluxation) • Spinal stenosis • Deformities (i.e. scoliosis, kyphosis, lordosis whether neuromuscular or related to deficient posterior elements) • Tumors (neoplastic disease) • Pseudoarthrosis • Failed previous fusion.
Comparison of the device to predicate device(s):	The Synthes ArcoFix System is a result of design modifications to the predicate devices. It is substantially equivalent to the predicates in design, function, material, and intended use.
Performance Date (Non-Clinical and/or Clinical):	*Non-Clinical Performance and Conclusions:* Bench testing results demonstrate that the Synthes ArcoFix System is substantially equivalent to the predicate devices. *Clinical Performance and Conclusions:* Clinical data and conclusions were not needed for this device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 23 2008

Synthes Spine CO. LP
% Ms. Kirsten Stowell
Associate Regulatory Affairs Specialist
1302 Wrights Lane East
West Chester, Pennsylvania 19380

Re: K080020/S002
Trade/Device Name: Synthes ArcoFix System
Regulation Number: 21 CFR 888.3060
Regulation Names: Spinal intervertebral body fixation orthosis
Regulatory Class: II
Product Code: KWQ
Dated: May 15, 2008
Received: May 19, 2008

Dear Ms. Stowell:

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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the 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

4 Indications for Use Statement

510(k) Number: K080020
(if known)

Device Name: Synthes ArcoFix System

Indications for Use:

The Synthes ArcoFix System is indicated for use, via the lateral or anterolateral surgical approach, in the treatment of thoracic and thoracolumbar (T1-L5) spine instability as a result of the following:

- Degenerative Disc Disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies)
- Spondylolisthesis
- Spondylolysis
- Fracture (including dislocation and subluxation)
- Spinal stenosis
- Deformities (i.e. scoliosis, kyphosis, lordosis whether neuromuscular or related to deficient posterior elements)
- Tumors (neoplastic disease)
- Pseudoarthrosis
- Failed previous fusion.

Prescription Use X (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 IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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