K072434

5a 510(k) Summary – OC Fusion System

JAN 10 2008

510(k) Summary	
Name of Firm:	Synthes Spine 1302 Wrights Lane East West Chester, PA 19380
510(k) Contact:	Susan Lewandowski Manager, Spine Regulatory Affairs Telephone: 610-719-5712 Facsimile: 610-719-5102 Email: Lewandowski.susan@synthes.com
Date Prepared:	November 2007
Trade Name:	Synthes OC Fusion System
Common Name:	Posterior, Cervical, Non-pedicle System
Classification:	21 CFR 888.3050 Spinal Interlaminal Fixation Orthosis Class II Orthopaedic and Rehabilitation Devices Panel Product Code KWP
Predicate Device(s):	K053418 Synthes OC Fusion System
Device Description:	The Synthes OC Fusion System consists of occipital plates, occipital screws, occipital clamps, and rods intended to provide stabilization to promote fusion of the occipital-cervical junction. This system allows an occipital-cervical construct of either the occipital plate and rods or occipital clamps and rods. Rods are connected to the occipital plate or occipital clamps using a locking screw. A complete occipital-cervical-thoracic construct can be created by using hooks (C1-T3) that have been previously cleared within the Synthes CerviFix System, Synthes Axon System, and Synthes Synapse System. The occipital bone screws are available in 4.5mm and 5.0mm diameters in lengths from 4mm to 18mm. Variable angle screw insertion is possible. The occipital clamps are available in either a one-hole or two-hole configuration. The occipital plate is available in two sizes in either a medial or lateral configuration for a total of four available plates.

510(k) Summary	
	The plates are manufactured from commercially pure Titanium, grade 4. The rod connection points (rod clamps) in the plate are manufactured from Titanium Aluminum Niobium (Ti-6Al-7Nb) as are the occipital clamps, rods, and occipital screws.
Intended Use / Indications for Use:	Synthes OC Fusion System is intended to provide stabilization to promote fusion of the occipital-cervical junction. A complete occipital-cervical-thoracic construct can be created by using hooks (C1-T3) that have been previously cleared within the Synthes CerviFix System, Synthes Axon System, and Synthes Synapse System. Synthes OC Fusion System is indicated for the following: DDD of the cervical vertebrae (neck pain of discogenic origin with degeneration of the disc as confirmed by patient history and radiographic studies), spondylolisthesis, spinal stenosis, atlanto/axial fracture with instability, occipital-cervical dislocation, revision of previous cervical spine surgery, and tumors (primary and metastatic) The use of screws is limited to placement in the occiput. Screws are not intended to be placed in the cervical spine.
Comparison of the technological characteristics of the device to predicate device(s):	The Synthes OC Fusion 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 Data (Nonclinical and/or Clinical):	*Non-Clinical Performance and Conclusions:* Bench testing results demonstrate that the Synthes OC Fusion System is substantially equivalent to the predicate devices. *Clinical Performance and Conclusions:* Clinical data and conclusions were not needed for this device.

5b 510(k) Summary – Synapse System

Name of Firm:	Synthes Spine 1302 Wrights Lane East West Chester, PA 19380
510(k) Contact:	Susan Lewandowski Manager, Spine Regulatory Affairs Telephone: 610-719-5712 Facsimile: 610-719-5102 Email: lewandowski.susan@synthes.com
Date Prepared:	November 2007
Trade Name:	Synthes Synapse System
Common Name:	Posterior Cervical System
Classification:	21 CFR 888.3050 – Spinal Interlaminal Fixation Orthosis Class II Orthopaedic and Rehabilitation Devices Panel Product Code KWP 21 CFR 888.3070 – Pedicle Screw Spinal System Class II Orthopaedic and Rehabilitation Devices Panel Product Codes MNH, MNI
Predicate Device:	K070573 Synthes Synapse System
Device Description:	The Synthes Synapse System consists of cancellous and cortex polyaxial screws, hooks, rods, transverse bars, parallel connectors, transconnectors, and locking screws. These implants are designed for fixation of the cervical, and/or upper thoracic spine (C1 – T3). A complete occipital-cervical-thoracic construct can be created by using components that have been previously cleared within the Synthes CerviFix System, Synthes Axon System, and Synthes OC Fusion System. The implants are manufactured from Titanium Aluminum Niobium TAN (Ti-6Al-7Nb) ASTM F1295, the same as the predicate device.
Intended Use / Indications for Use:	Synthes Synapse System is indicated for the following: *Hooks, Plate/Rods, Plates, Rods and Screws*

	When intended to promote fusion of the cervical spine and occipitocervical junction (occiput-T3), the plate/rod, plates, rod, hook and screw (3.2 mm cortex) components of the Synthes Cervifix, Axon, OC Fusion and Synapse Systems are indicated for the following: • Degenerative Disc Disease (DDD) (defined as neck pain of discogenic origin with degeneration of the disc as confirmed by patient history and radiographic studies) • Spondylolisthesis • Spinal Stenosis • Fracture/dislocation • Atlantoaxial fracture with instability • Occipitocervical dislocation • Revision of previous cervical spine surgery • Tumor When used to treat these cervical and occipitocervical conditions, screws are limited to occipital fixation only. *Hooks and Rods* The rod and hook components are also intended to provide stabilization to promote fusion following reduction of fracture/dislocation or trauma in the cervical/upper thoracic (C1-T3) spine. *Rods, Clamps, Screws, Nuts, Variable Axis Screws, Locking Screws, and Transverse Bars* The rods, clamps, screws, nuts, variable axis screws, locking screws, and transverse bars are intended to promote fusion following reduction of fracture/dislocation or trauma in the upper thoracic spine (T1-T3). The use of these screws (3.5 mm, 4.0 mm and 4.5 mm cancellous, and 3.5 mm and 4.2 mm cortex) is limited to placement in T1-T3 in treating thoracic conditions only. They are not intended to be placed in or treat conditions involving the cervical spine. The Synthes CerviFix, Axon, and Synapse Systems can also be linked to the Synthes Universal Spinal System using the 3.5 mm/6.0 mm parallel connectors from that system and via the CerviFix tapered rods using lamina hooks, transverse process hooks, pedicle hooks, 4.2 mm screws and the 5.0 mm/6.0 mm parallel connector.

	Warning: This device is not intended for screw attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic, or lumbar spine.
Comparison of the technological characteristics of the device to the predicate device:	The Synthes Synapse System is a result of design modifications to the predicate device. It is substantially equivalent to the predicate in design, function, material and intended use.
Performance Data (Nonclinical and/or Clinical)	*Non-Clinical Performance and Conclusions:* Bench testing results demonstrate that the Synthes Synapse System is substantially equivalent to the predicate device. *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

JAN 10 2008

Synthes Spine
% Ms. Susan Lewandowski
Manager, Spine Regulatory Affairs
1302 Wrights Lane East
West Chester, PA 19380

Re: K072434
Trade/Device Name: Synthes OC Fusion and Synapse Systems
Regulation Number: 21 CFR 888.3070
Regulation Names: Pedicle screw spinal system
Regulatory Class: II
Product Code: MNI, MNH, KWP
Dated: November 30, 2007
Received: December 3, 2007

Dear Ms. Lewandowski:

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

4a Indications for Use Statement – OC Fusion System

510(k) Number: (if known) K_____

Device Name: Synthes OC Fusion System

Indications for Use: The Synthes OC Fusion System is intended to provide stabilization to promote fusion of the occipital-cervical junction. A complete occipital-cervical-thoracic construct can be created by using hooks (C1-T3) that have been previously cleared within the Synthes CerviFix System, Synthes Axon System, and Synthes Synapse System.

Synthes OC Fusion System is indicated for the following:

- Degenerative disc disease of the cervical vertebrae (neck pain of discogenic origin with degeneration of the disc as confirmed by patient history and radiographic studies)
- Spondylolisthesis
- Spinal Stenosis
- Fracture/Dislocation
- Atlanto/axial fracture with instability
- Occipital-cervical dislocation
- Revision of previous cervical spinal surgery
- Tumors (primary and metastatic)

The use of screws is limited to placement in the occiput. Screws are not intended to be placed in the cervical spine.

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

510(k) Number K072434

Indications for Use Statement – Synapse System

510(k) Number: K072434
(if known)

Device Name: **Synthes Synapse System**

Indications for Use: Synthes Synapse System is indicated for the following:

Hooks, Plate/Rods, Plates, Rods and Screws
When intended to promote fusion of the cervical spine and occipitocervical junction (occiput-T3), the plate/rod, plates, rod, hook and screw (3.2 mm cortex) components of the Synthes Cervifix, Axon, OC Fusion and Synapse Systems are indicated for the following:

- Degenerative Disc Disease (DDD) (defined as neck pain of discogenic origin with degeneration of the disc as confirmed by patient history and radiographic studies)
- Spondylolisthesis
- Spinal Stenosis
- Fracture/dislocation
- Atlantoaxial fracture with instability
- Occipitocervical dislocation
- Revision of pervious cervical spine surgery
- Tumor

When used to treat these cervical and occipitocervical conditions, screws are limited to occipital fixation only.

Hooks and Rods
The rod and hook components are also intended to provide stabilization to promote fusion following reduction of fracture/dislocation or trauma in the cervical/upper thoracic (C1-T3) spine.

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Prescription Use **X** (21 CFR 801 Subpart D) AND / OR Over-the-Counter Use (21 CFR 801 Subpart C)

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

510(k) Number K072434

Rods, Clamps, Screws, Nuts, Variable Axis Screws, Locking Screws, and Transverse Bars
The rods, clamps, screws, nuts, variable axis screws, locking screws, and transverse bars are intended to promote fusion following reduction of fracture/dislocation or trauma in the upper thoracic spine (T1-T3).

The use of these screws (3.5 mm, 4.0 mm and 4.5 mm cancellous, and 3.5 mm and 4.2 mm cortex) is limited to placement in T1-T3 in treating thoracic conditions only. They are not intended to be placed in or treat conditions involving the cervical spine.

The Synthes CerviFix, Axon, and Synapse Systems can also be linked to the Synthes Universal Spinal System using the 3.5 mm/6.0 mm parallel connectors from that system and via the CerviFix tapered rods using lamina hooks, transverse process hooks, pedicle hooks, 4.2 mm screws and the 5.0 mm/6.0 mm parallel connector.

Warning: This device is not intended for screw attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic, or lumbar spine.

Prescription Use **X** (21 CFR 801 Subpart D)	AND / OR	Over-the-Counter Use (21 CFR 801 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Barbara Ruehn

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

510(k) Number K072434