JUL 10 2009

2 510(k) Summary

2.1 Synapse 4.0mm System 510K Summary

510(k) Summary	
Name of Firm:	Synthes Spine 1302 Wrights Lane East West Chester, PA 19380
510(k) Contact:	Stacey Bonnell Regulatory Affairs Specialist Telephone: 610-719-5895 Facsimile: 610-719-5102 Email: bonnell.stacey@synthes.com
Date Prepared:	June 8, 2009
Trade Name:	Synthes Synapse 4.0mm System
Common Name:	Posterior Cervical System
Classification:	21 CFR 888.3050 – Spinal Interlaminal Fixation Orthosis 21 CFR 888.3070 – Pedicle Screw Spinal System Class II; Orthopaedic and Rehabilitation Devices Panel Product Code(s): KWP, MNI & MNH
Predicate Device(s):	Synthes Synapse 4.0mm System is substantially equivalent to similar previously cleared devices.
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 provide stabilization as an adjunct to 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 skeletally mature patients using allograft and/or autograft 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 and 4.0 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 (T4-T12), or lumbar spine.
Comparison of the technological characteristics of the device to the predicate device:	Synthes Synapse System 4.0mm components are a result of design modifications to the predicate devices. The 4.0mm components are substantially equivalent to the predicates in design, function, material and intended use.
Performance Data (Nonclinical and/or Clinical)	*Non-Clinical Performance and Conclusions:* Documentation was provided which demonstrated the Synapse 4.0mm System to be substantially equivalent to previously cleared devices. The substantial equivalence is based upon equivalence in intended use, indications, anatomic sites, performance, and material of manufacture. *Clinical Performance and Conclusions:* Clinical data and conclusions were not needed for this device.

2.2 OC Fusion 4.0mm System 510K Summary

510(k) Summary	
Name of Firm:	Synthes Spine 1302 Wrights Lane East West Chester, PA 19380
510(k) Contact:	Stacey Bonnell Regulatory Affairs Specialist Telephone: 610-719-5895 Facsimile: 610-719-5102 Email: bonnell.stacey@synthes.com
Date Prepared:	June 8, 2009
Trade Name:	Synthes OC Fusion 4.0mm 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):	Synthes OC Fusion 4.0mm System is substantially equivalent to similar previously cleared devices.
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-thoracic 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) and screws (T1-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. The occipital clamps are manufactured from both commercially pure Titanium, grade 4 and Titanium Aluminum Niobium (Ti-6Al-7Nb). The plates are manufactured from commercially pure Titanium, grade 2. The two bodies in the plate that serve as rod connection points are manufactured from Titanium Aluminum Niobium (Ti-6Al-7Nb) as are the rods, and occipital screws.
Intended Use / Indications for Use:	Synthes OC Fusion System is intended to provide stabilization as an adjunct to fusion of the occipital-cervical junction. A complete occipital-cervical-thoracic construct can be created by using hooks (C1-T3) and screws (T1-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 skeletally mature patients

510(k) Summary	
	using allograft and/or autograft 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 4.0mm components are a result of design modifications to the predicate devices. These 4.0mm components are substantially equivalent to the predicates in design, function, material and intended use.
Performance Data (Nonclinical and/or Clinical):	*Non-Clinical Performance and Conclusions:* Documentation was provided which demonstrated the OC Fusion 4.0mm System to be substantially equivalent to previously cleared devices. The substantial equivalence is based upon equivalence in intended use, indications, anatomic sites, performance, and material of manufacture. *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

Synthes (USA)
% Ms. Stacey Bonnell
Regulatory Affairs Specialist
1302 Wrights Lane East
West Chester, Pennsylvania 19380

JUL 10 2009

Re: K091689
Trade/Device Name: Synthes Synapse 4.0mm System
Regulation Number: 21 CFR 888.3050
Regulation Name: Spinal interlaminal fixation orthosis
Regulatory Class: II
Product Code: KWP, MNI, MNH
Dated: June 8, 2009
Received: June 10, 2009

Dear Ms. Bonnell:

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 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/cdrh/mdr/ for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic,
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

1 Indications for Use Statement

1.1 Synapse 4.0 Indications for Use

510(k) Number: K091689
(if known)

Device Name: Synthes Synapse 4.0mm System

Hooks, Plate/Rods, Plates, Rods and Screws

When intended to provide stabilization as an adjunct to 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 skeletally mature patients using allograft and/or autograft 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.

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)

(EXT for MKM)

(Division Sign-Off)
Division of Surgical, Orthopedic, and Restorative Devices

510(k) Number K091689

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 and 4.0 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 (T4-T12), or lumbar 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)

(EXT for MXM)

Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K091689

1.2 OC Fusion 4.0 Indications for Use

510(k) Number: K091689
(if known)

Device Name: OC Fusion 4.0mm System

Indications for Use:

The Synthes OC Fusion System is intended to provide stabilization as an adjunct to fusion of the occipital-cervical junction. A complete occipital-cervical-thoracic construct can be created by using hooks (C1-T3) and screws (T1-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 skeletally mature patients using allograft and/or autograft 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)

(EXT for MKM)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K091689