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Spine

4 510(k) Summary

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510(k) Summary	
Name of Firm:	Synthes Spine 1302 Wrights Lane East West Chester, PA 19380
510(k) Contact:	Amnon Talmor Spine Regulatory Affairs Specialist Telephone: 610-719-5446 Facsimile: 610-719-5102 Email: talmora@synthes.com
Date Prepared:	March 3, 2010
Trade Name:	Synthes Matrix System
Classification:	21 CFR 888.3050–Spinal interlaminar fixation orthosis 21 CFR 888.3060–Spinal intervertebral body fixation orthosis 21 CFR 888.3070–Pedicle screw spinal system Class III Orthopaedic and Rehabilitation Devices Panel Product Code: NKB, MNH, MNI, KWQ, KWP
Predicate Devices:	Synthes Univeral Sacral System, K963045 Synthes Matrix System, K092929 Synthes Pangea System, K052151 Synthes Click'X Monoaxial, K031175 Synthes Dual Opening USS, K023675 Synthes USS, K022949 Synthes USS Iliosacral and USS Polyaxial, K082572 Synthes CerviFix, K001864 Synthes Synapse System, K070573
Device Description:	The Synthes Matrix System is an addition to Synthes' existing posterior thoracolumbar spine systems. The Matrix System consists of a family of non-cervical spinal fixation devices intended for posterior pedicle screw fixation (T1-S2), posterior hook fixation (T1-L5) or anterolateral fixation (T8-L5). The implants include pedicle bone screws, polyaxial pedicle screws, monoaxial pedicle screws, polyaxial heads, reduction screws, reduction heads, locking caps, transconnectors, transverse bars, rods and hooks. The implants are primarily manufactured from titanium (ASTM F67 – 06), titanium alloy (ASTM F1295 – 05), cobalt-chromium-molybdenum alloy (ASTM F1537 – 08) or nitinol (ASTM F2063 – 05), similar to the predicates. The subject of this submission is the addition of transverse bars and tapered rods.
Intended Use/ Indications for Use:	The Synthes USS are non-cervical spinal fixation devices intended for posterior pedicle screw fixation (T1-S2/ilium), posterior hook fixation (T1-L5), or anterolateral fixation (T8-L5). Pedicle screw fixation is limited to skeletally mature patients with the exception of the Small Stature USS, which includes small stature and pediatric patients. These devices are indicated as an adjunct to fusion for all of the following indications: degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by

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	history and radiographic studies), spondylolisthesis, trauma (i.e., fracture or dislocation), deformities or curvatures (i.e., scoliosis, kyphosis, and/or lordosis, Scheuermann's Disease), tumor, stenosis, and failed previous fusion (pseudoarthrosis). When treating patients with Degenerative Disc Disease (DDD), transverse bars are not cleared for use as part of the posterior pedicle screw construct. When used with the 3.5/6.0 mm parallel connectors, the Synthes USS 6.0 mm rod systems can be linked to the CerviFix 3.5 mm Systems. In addition, when used with 3.5/5.0 mm parallel connectors, the Synthes Small Stature USS can be linked to the CerviFix 3.5 mm Systems. When used with the 5.0/6.0 mm parallel connectors, the Synthes Small Stature USS can be linked to the Synthes USS 6.0 mm rod systems. When used with the 3.5/6.0 mm and 4.0/6.0 mm tapered rods, the Synthes USS 6.0 mm rod systems can be linked to the CerviFix 3.5 mm and 4.0 mm Systems, respectively. When used with the 3.5/5.5 mm and 4.0/5.5 mm tapered rods, Matrix can be linked to the CerviFix 3.5 mm and 4.0 mm Systems, respectively. When used with the 5.5/6.0 mm tapered rods, the Synthes USS 6.0 mm rod systems can be linked to the Matrix System. In addition, Synthes USS 6.0 mm rod systems can be interchanged with all USS 6.0 mm rods and transconnectors. *Synthes USS* o 6.0 mm Rod Systems: USS Side-Opening, USS Dual-Opening, USS VAS variable axis components, USS Fracture, Click'X, Click'X Monoaxial, Pangea, Pangea Monoaxial, USS Polyaxial, USS Iliosacral, ClampFix o 5.5 mm Rod System: Matrix o 5.0 mm Rod System: USS Small Stature *CerviFix* o 3.5 mm Rod Systems: CerviFix, Axon, Synapse o 4.0 mm Rod System: Synapse
Comparison of the technological characteristics of the device to the predicate device:	The design features, material, and indications for use of the subject Matrix System is substantially equivalent to the predicate devices identified. Additionally, the safety and effectiveness of this system is adequately supported by documentation within this premarket notification.
Performance Data (Non-Clinical and/or Clinical):	Synthes conducted the following non-clinical testing: static compression bend, static torsion, and dynamic compression bend testing in accordance with ASTM F1717 – 09. The conclusions drawn from testing demonstrate that the Matrix System is as safe and effective and performs as well as or better than the predicate devices identified. Clinical data was not needed for this device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

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Synthes Spine
% Mr. Amon Talmor
Regulatory Affairs Specialist
1302 Wrights Lane East
West Chester, Pennsylvania 19380

Re: K100634
Trade/Device Name: Synthes Matrix System
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle screw spinal system
Regulatory Class: Class III
Product Code: NKB, MNI, MNH, KWP, KWQ
Dated: June 25, 2010
Received: June 28, 2010

Dear Mr. Talmor:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

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/MedicalDevices/Safety/ReportaProblem/default.htm 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 (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

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

Enclosure

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4 Indications for Use Statement

510(k) Number: K100634
Device Name: Synthes Matrix System

The Synthes USS are non-cervical spinal fixation devices intended for posterior pedicle screw fixation (T1-S2/ilium), posterior hook fixation (T1-L5), or anterolateral fixation (T8-L5). Pedicle screw fixation is limited to skeletally mature patients with the exception of the Small Stature USS, which includes small stature and pediatric patients. These devices are indicated as an adjunct to fusion for all of the following indications: degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, trauma (i.e., fracture or dislocation), deformities or curvatures (i.e., scoliosis, kyphosis, and/or lordosis, Scheuermann's Disease), tumor, stenosis, and failed previous fusion (pseudoarthrosis).

When treating patients with Degenerative Disc Disease (DDD), transverse bars are not cleared for use as part of the posterior pedicle screw construct.

When used with the 3.5/6.0 mm parallel connectors, the Synthes USS 6.0 mm rod systems can be linked to the CerviFix 3.5 mm Systems. In addition, when used with 3.5/5.0 mm parallel connectors, the Synthes Small Stature USS can be linked to the CerviFix 3.5 mm Systems. When used with the 5.0/6.0 mm parallel connectors, the Synthes Small Stature USS can be linked to the Synthes USS 6.0 mm rod systems.

When used with the 3.5/6.0 mm and 4.0/6.0 mm tapered rods, the Synthes USS 6.0 mm rod systems can be linked to the CerviFix 3.5 mm and 4.0 mm Systems, respectively. When used with the 3.5/5.5 mm and 4.0/5.5 mm tapered rods, Matrix can be linked to the CerviFix 3.5 mm and 4.0 mm Systems, respectively. When used with the 5.5/6.0 mm tapered rods, the Synthes USS 6.0 mm rod systems can be linked to the Matrix System.

In addition, Synthes USS 6.0 mm rod systems can be interchanged with all USS 6.0 mm rods and transconnectors.

Synthes USS

- 6.0 mm Rod Systems: USS Side-Opening, USS Dual-Opening, USS VAS variable axis components, USS Fracture, Click'X, Click'X Monoaxial, Pangea, Pangea Monoaxial, USS Polyaxial, USS Iliosacral, ClampFix
- 5.5 mm Rod System: Matrix
- 5.0 mm Rod System: USS Small Stature

CerviFix

- 3.5 mm Rod Systems: CerviFix, Axon, Synapse
- 4.0 mm Rod System: Synapse

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 Surgical, Orthopedic,
and Restorative Devices

510(k) Number K100634