DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
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March 29, 2017

Synthes USA Products, LLC
Mr. Eugene Bang
Regulatory Affairs Associate
325 Paramount Drive
Raynham, Massachusetts 02767

Re: K170654
Trade/Device Name: USS System
Regulation Number: 21 CFR 888.3070
Regulation Name: Thoracolumbosacral pedicle screw system
Regulatory Class: Class II
Product Code: NKB, KWP, KWQ
Dated: March 2, 2017
Received: March 3, 2017

Dear Mr. Bang:

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 contact the Division of Industry and Consumer Education 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. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 Industry and Consumer Education 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,

Mark N. Melkerson -S

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

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K170654

Device Name
USS System

Indications for Use *(Describe)*

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 mm/6.0mm parallel connectors, the Synthes USS 6.0 mm rod systems can be linked to the CerviFix 3.5mm Systems. In addition, when used with 3.5 mm/5.0mm parallel connectors, the Synthes Small Stature USS can be linked to the CerviFix 3.5mm Systems. When used with the 5.0 mm/6.0mm parallel connectors, the Synthes Small Stature USS can be linked to the Synthes USS 6.0 mm rod systems. When used with the 5.5 mm/6.0mm parallel or extension connectors, Synthes USS 5.5 mm rod systems can be linked to the Synthes USS 6.0 mm rod systems. 5.5 mm/5.5 mm parallel or extension connectors can be used to link all Synthes USS 5.5 mm rod systems to one another. 6.0 mm/6.0mm parallel or extension connectors can be used to link all Synthes USS 6.0 mm rod systems to one another.

Rod-to-rod connectors can be used to link all Synthes USS 5.5 mm rod systems to one another.

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

In addition, Synthes USS 6.0 mm rod systems can be interchanged with all USS 6.0 mm rods and transconnectors except Synthes 6.0 mm cobalt-chromium-molybdenum alloy rods, which can only be used with USS Monoaxial Dual Core (Single-Opening) Screws. Synthes USS 5.5 mm rod systems can be interchanged with all USS 5.5 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, USS Polyaxial, USS Iliosacral, ClampFix
- 5.5 mm Rod Systems: Matrix
- 5.0 mm Rod System: USS Small Stature

CerviFix

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

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

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510(k) Summary	
Submitter	Synthes USA Products, LLC 325 Paramount Drive Raynham, MA 02767
Contact Person	Eugene Bang Regulatory Affairs Associate Telephone: (508) 977-3966 Fax: (508) 828-3797
Date Prepared	March 2, 2017
Trade Name	USS System
Device Class	Class II
Product Code	NKB, KWQ, KWP
Regulation Number and Description	21 CFR 888.3050 – Spinal interlaminal fixation orthosis 21 CFR 888.3060 – Spinal intervertebral body fixation orthosis 21 CFR 888.3070 – Thoracolumbosacral pedicle screw system (primary regulation)
Predicate Devices	Synthes USS System – K082572 (primary predicate) Synthes Pangea System – K103287
Device Description	The Synthes USS is a comprehensive system of spinal implants and instruments for non-cervical spinal fixation devices intended for posterior pedicle screw fixation (T1- S2/ilium), posterior hook fixation (T1-L5), or anterolateral fixation (T8-L5). Currently cleared components of the system include monoaxial and polyaxial pedicle screws, rods, hooks, locking caps, transconnectors, transverse bars, parallel connectors, and extension connectors.

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 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 mm/6.0mm parallel connectors, the Synthes USS 6.0 mm rod systems can be linked to the CerviFix 3.5mm Systems. In addition, when used with 3.5 mm/5.0mm parallel connectors, the Synthes Small Stature USS can be linked to the CerviFix 3.5mm Systems. When used with the 5.0 mm/6.0mm parallel connectors, the Synthes Small Stature USS can be linked to the Synthes USS 6.0 mm rod systems. When used with the 5.5 mm/6.0mm parallel or extension connectors, Synthes USS 5.5 mm rod systems can be linked to the Synthes USS 6.0 mm rod systems. 5.5 mm/5.5 mm parallel or extension connectors can be used to link all Synthes USS 5.5 mm rod systems to one another. 6.0 mm/6.0mm parallel or extension connectors can be used to link all Synthes USS 6.0 mm rod systems to one another. Rod-to-rod connectors can be used to link all Synthes USS 5.5 mm rod systems to one another. When used with the 3.5 mm/6.0mm and 4.0 mm/6.0mm 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 mm/5.5mm and 4.0 mm/5.5 mm tapered rods, the Synthes USS 5.5 mm rod systems can be linked to the CerviFix 3.5 mm and 4.0 mm Systems, respectively. When used with the 5.5 mm/6.0mm tapered rods, the Synthes USS 6.0 mm rod systems can be linked to the Synthes USS 5.5 mm rod systems. In addition, Synthes USS 6.0 mm rod systems can be interchanged with all USS 6.0 mm rods and transconnectors except Synthes 6.0 mm cobalt-chromium-molybdenum alloy rods, which can only be used with USS Monoaxial Dual Core (Single-Opening) Screws. Synthes USS 5.5 mm rod systems can be interchanged with all USS 5.5 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, USS Polyaxial, USS Iliosacral, ClampFix • 5.5 mm Rod Systems: Matrix • 5.0 mm Rod System: USS Small Stature CerviFix • 3.5 mm Rod Systems: CerviFix, Axon, Synapse • 4.0 mm Rod System: Synapse

Materials	The USS monoaxial screws are manufactured from titanium alloy (Ti-6Al-7Nb) per ASTM F1295 and the rods are manufactured from Cobalt-28 Chromium-6 Molybdenum Alloy (Co-28Cr-6Mo) per ASTM F1537.
Summary of Technological Characteristics	The technological characteristics of the subject devices remain unchanged from their currently marketed predicate versions in their design, material, performance, and intended use.
Performance Data	In order to characterize the USS screw and rod to establish their substantial equivalence, mechanical testing was conducted in a comparative manner. The mechanical properties of the USS screws and rods were evaluated through the following tests in accordance with ASTM F1717-15 Standard Test Methods for Spinal Implant Constructs in a Vertebrectomy Model: dynamic compression bending.
Conclusion	The substantial equivalence justification provided in the submission demonstrates that the devices are safe and effective as the predicate devices because the intended use and technological characteristics remain unchanged.