510(K) SUMMARY

JAN 16 2014

A. Submitter Information

Submitter: Synthes USA Products LLC
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West Chester, Pennsylvania 19380

Contact Person: Laura Bleyendaal
DePuy Synthes Spine
325 Paramount Drive
Raynham, MA 02767
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B. Date Prepared

January 15, 2014

C. Device Name

Trade/Proprietary Name: Synapse System
Common/Usual Name: Spinal interlaminal fixation orthosis

Device Classification and Regulation: Class II, per 21 CFR §888.3050

Subsequent Regulation: 21 CFR §888.3070

Classification Product and Panel Code: KWP; Orthopedic

Subsequent Product and Panel Codes: MNI; Orthopedic
MNH; Orthopedic

D. Predicate Device Name

Trade name: Synthes Synapse System (most recently cleared K091689)
Sierra™ System (K062934, K080526)

Altius™ OCT System (K033961, K043229)

E. Device Description

The Synapse System is a hook and pedicle screw spinal system which is designed to provide spinal fixation to allow for stabilization of spinal segments in skeletally mature patients as an adjunct to fusion. The Synapse System is composed of multiple components to allow the surgeon to build an implant system to fit the patient's anatomical and physiological requirements. The Axon System and Cervifix System also included in the indications for use statement are additional hook and pedicle screw spinal systems. These systems consist of anchors including bone screws, pedicle screws and hooks; interconnection mechanisms including locking screws, set screws, parallel rod connectors, clamps, transverse bars, rod collars and nuts; longitudinal members including rods and rod/plates; and transverse connectors including transconnectors. These system components are implanted using class I surgical instruments.

F. Indications for Use

These Systems are intended 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.

G. Summary of Similarities and Differences in Technological Characteristics, Performance and Intended Use

The indications for use, intended use and technological characteristics, such as design and material, of the proposed curved rods are the same as, or similar to, those of the predicate devices from the Synapse System, Sierra™ System and Altius™ OCT System.

H. Materials

The proposed curved rods are manufactured from the same material, titanium aluminum niobium (Ti-6Al-7Nb (TAN)), as the previously cleared Synapse System curved rods. The material conforms to ASTM F-1295-11 Standard Specification for Wrought Titanium-6Aluminum-7Niobium Alloy for Surgical Implant Applications and ISO 5832-11 Implants for surgery- Metallic materials—Part 11: Wrought titanium 6-aluminum 7-niobium alloy.

I. Performance Data

A rationale is provided in place of performance testing for the proposed curved rods.

J. Conclusion

The substantial equivalence justification demonstrates that the proposed curved rods are substantially equivalent to the predicate devices in the Synapse System, the Sierra™ System and the Altius™ OCT System.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

January 16, 2014

Synthes USA Products, LLC
Ms. Laura Bleyendaal
Regulatory Affairs Associate
325 Paramount Drive
Raynham, Massachusetts 02767

Re: K133698
Trade/Device Name: Synapse System
Regulation Number: 21 CFR 888.3050
Regulation Name: Spinal interlaminal fixation orthosis
Regulatory Class: Class II
Product Code: KWP, MNI, MNH
Dated: December 20, 2013
Received: December 23, 2013

Dear Ms. Bleyendaal:

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 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. 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,

Lori A. Wiggins

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

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K133698

Device Name: Synapse System

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Prescription Use ___X___ AND/OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of Center for Devices and Radiological Health (CDRH)

Zane W. Wyatt -S

(Division Sign-Off)
Division of Orthopedic Devices
510(k) Number: K133698