



Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

Synthes USA Products, LLC
Mr. Eric Zhu
Regulatory Affairs Specialist
325 Paramount Drive
Raynham, Massachusetts 02767

June 18, 2015

Re: K151276

Trade/Device Name: DePuy Synthes T-PAL Ti Spacer
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: MAX
Dated: May 12, 2015
Received: May 13, 2015

Dear Mr. Zhu:

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" (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 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 yours,

Mark N. Melkerson -S

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

Enclosure

510(k) Summary

A. Submitter Information

Manufacturer: Synthes Production GmbH
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Switzerland

Submitter: Synthes USA Products, LLC
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Raynham MA 02767

Contact Person: Eric Zhu
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B. Date Prepared June 17, 2015

C. Device Name

Trade/Proprietary Name: DePuy Synthes T-PAL Ti Spacer

Common/Usual Name: Spinal Intervertebral Body Fusion Device

Classification Name: Intervertebral Fusion Device with Bone Graft,
Lumbar Intervertebral Body Fusion Device
per 21 CFR §888.3080
Product Code MAX (Intervertebral body fusion
device)

D. Predicate Device Name

Predicate Trade name: Synthes T-PAL Spacer (K100089)

Reference Device: Patriot Signature[®] Ti Spacer (K122097)

E. Device Description

The DePuy Synthes T-PAL Ti Spacer is an interbody fusion device used in conjunction with supplemental fixation to provide structural stability in skeletally mature individuals following total or partial discectomy. Previously, only T-PAL Spacers manufactured from PEEK (With TAN marker pins) material were available. The subject T-PAL Ti spacers will be manufactured entirely of TAN per ASTM F1295. The T-PAL Ti Spacer is available in two footprints and a range of heights and is angulated 5° to accommodate the lordotic curve (except for the smallest height of each footprint, which does not have a lordotic angle). Pyramidal teeth that assist in stabilization of the construct are located on the inferior and superior surfaces of the spacers. These teeth are oriented along a contour that follows the curve of the implant to assist in implantation. A bullet-nose design also facilitates self-distraction and ease of insertion. The open architecture of the devices allows them to be packed with autogenous bone graft material, i.e. autograft.

F. Intended Use

The DePuy Synthes T-PAL Ti Spacer is indicated for use in patients with degenerative disc disease (DDD) at one or two contiguous levels from L2 to S1 whose condition requires the use of interbody fusion combined with supplemental fixation. The interior of the T-PAL Spacers should be packed with autogenous bone graft (i.e. autograft).

DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. These patients should be skeletally mature and have had six months of non-operative treatment.

The T-PAL Spacers are intended to be used with DePuy Synthes supplemental fixation.

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

The proposed modifications to the Synthes T-PAL Spacer are identical to the predicate device (K100089) except for the material change, sterilization modality change, and a minor modification to the design. The indications, performance, and technology remain identical to the predicate systems. We are not replacing the predicate device with the proposed Titanium Spacer device, but we are making additional T-PAL Ti Spacers available for the market.

G. Materials

T-PAL Ti Spacers will be manufactured from Ti-6Al-7Nb (TAN) ASTM F-1295 implant grade titanium alloy.

H. Performance Data

The minor modification to the design of the device and material change do not change the technological characteristics of the device. A Finite Element Analysis simulating Static/Dynamic Axial Compression and Compression Shear testing demonstrated that the proposed modifications do not introduce a new worst case.

I. Conclusion

The Substantial Equivalence Justification demonstrate that the subject devices are substantially equivalent to the predicate devices because the intended use remain unchanged and technological characteristics of the subject device are similar to the predicate. The Finite Element Analysis and post market data further demonstrates that the material change and modification to the design do not introduce any new questions of safety and effectiveness.