December 6, 2018

DePuy Synthes Spine
Ms. Rozanne Shirley
Regulatory Affairs Specialist
325 Paramount Drive
Raynham, Massachusetts 02767

Re: K181231
Trade/Device Name: DePuy Synthes T-PAL Spacer System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: MAX
Dated: November 5, 2018
Received: November 6, 2018

Dear Ms. Shirley:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Katherine D. Kavlock -S

for
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: *0613012020*
See *PRA Statement below.*

510(k) Number
K181231

Device Name
DePuy Synthes T-PAL Spacer System

Indications for Use *(Describe)*
The T-PAL 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 Spacer 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 nonoperative treatment.

The T-PAL Spacer is intended to be used with DePuy Synthes supplemental fixation.

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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary

A. Submitter Information

510(k) Sponsor:	Synthes USA, LLC 1101 Synthes Avenue Monument, CO 80132 USA
Submitter:	DePuy Synthes Spine 325 Paramount Drive Raynham, MA 02767
Contact Person:	Rozanne Shirley 325 Paramount Drive Raynham, MA 02767
Telephone number:	(508) 977-6304
Email:	rshirle1@its.jnj.com

B. Date Prepared

December 6, 2018

C. Device Name

Trade/Proprietary Name:	DePuy Synthes T-PAL Spacer System
Common/Usual Name:	Intervertebral Fusion Device with Bone Graft, Lumbar
Classification Name:	Intervertebral Fusion, per 21 CFR 888.3080
Product Code:	MAX

Predicate Device Name

Primary Predicate Trade Name:	T-PAL Spacer System (K100089)
Additional Predicate Device:	DePuy Synthes T-PAL Ti Spacer System (K151276)

D. Device Description

The T-PAL Spacer System is an interbody fusion device used in conjunction with supplemental internal fixation to provide structural stability in skeletally mature individuals following intervertebral discectomy. The T-PAL Applicator is used to insert the T-PAL Spacer into the disc space. The T-PAL Applicator is composed of an inner shaft and handle (outer shaft). The scope of this submission is to develop an additional T-PAL Applicator option for surgeons to

facilitate insertion of the T-PAL Spacer and final positioning in the interbody disc space.

E. Indications for Use

The T-PAL 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 Spacer 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 nonoperative treatment.

The T-PAL Spacer is intended to be used with DePuy Synthes supplemental fixation.

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

The intended use, method of sterilization, fundamental scientific technology, and function of the T-PAL Advanced Applicator is identical to the predicate devices, K100089 and K151276. The T-PAL Advanced Applicator has similar but not identical design and performance as the current T-PAL Applicator, due to minor modifications to the handle and inner shaft. The main difference between the predicate device and the subject device includes a modification to the T-PAL Advanced Applicator inner shaft to now have a biased claw design with an elongated finger and a higher pivoting angle to allow for greater flexibility in the angle of approach and to facilitate implant release. The minor modification to the width of the distal end of the T-PAL Advanced Applicator Handle is to accommodate for the new inner shaft, and current implants and trial spacers. In addition, there is a minor design modification to the base material of the distal end of the handle. The predicate device will not be replaced by the subject device in the market.

G. Materials

The T-PAL Applicator and T-PAL Advanced Applicator are manufactured from a medical grade stainless steel. The material used to manufacture the T-PAL Advanced Applicator Inner Shaft is identical to the predicate, T-PAL Applicator Inner Shaft. The T-PAL Applicator and T-PAL Advanced Applicator Handles are composed of silicone rubber and stainless steel. The stainless-steel material of the distal end of the T-PAL Advanced Applicator (outer shaft) is being modified from a 17-4 PH Stainless Steel to a Custom 465cw Stainless Steel. Other than this change, the materials and manufacturing of the subject device are identical to those of the predicate device.

H. Performance Data

The new T-PAL Advanced Applicator is a minor modification to the currently cleared T-PAL Applicator, the modification and does not change the fundamental scientific technology of the device. Based on a review of the performance data, the subject T-PAL Advanced Applicator does not represent a worst case from a mechanical testing standpoint. The mechanical testing simulated the insertion of the implant into an intervertebral body using the subject T-PAL Advanced Applicator. The performance acceptance criteria was met. The conclusion of the testing criteria demonstrates the subject device performs substantially equivalent to the predicate device and does not raise new questions of safety and effectiveness.

I. Conclusion

The subject device, T-PAL Advanced Applicator, is substantially equivalent to the predicate devices because the intended use remains unchanged due to the changes to the device and technological characteristics of the subject device are similar to the predicate. The insertion testing further demonstrates that the modifications to the design do not introduce any new questions of safety and effectiveness.