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

November 1, 2016

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

Re: K162358
Trade/Device Name: T-PAL Spacer System, T-PAL Titanium Spacer System, SYNFIX Evolution System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: MAX, OVD
Dated: August 22, 2016
Received: August 23, 2016

Dear Eugene 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)*

Device Name

T-PAL Spacer System

Indications for Use *(Describe)*

The T-PAL Spacer System is indicated for use as an intervertebral body fusion device in skeletally mature patients with degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies) at one or two contiguous levels of the lumbar spine (L2-S1). Additionally, the T-PAL Spacer System can be used in patients diagnosed with spinal deformities as an adjunct to fusion. These patients should be skeletally mature and have undergone six months of non-operative treatment prior to surgery. These implants are used to facilitate fusion in the lumbar spine using autogenous bone and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft. When used as an interbody fusion device these implants are intended for use with supplemental internal fixation systems.

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

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# Indications for Use

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

510(k) Number *(if known)*

Device Name

T-PAL Titanium Spacer System

Indications for Use *(Describe)*

The T-PAL Titanium Spacer System is indicated for use as an intervertebral body fusion device in skeletally mature patients with degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies) at one or two contiguous levels of the lumbar spine (L2-S1). Additionally, the T-PAL Titanium Spacer System can be used in patients diagnosed with spinal deformities as an adjunct to fusion. These patients should be skeletally mature and have undergone six months of non-operative treatment prior to surgery. These implants are used to facilitate fusion in the lumbar spine using autogenous bone and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft. When used as an interbody fusion device these implants are intended for use with supplemental internal fixation systems.

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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# Indications for Use

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

510(k) Number *(if known)*
K162358



Device Name
SYNFIX Evolution System

Indications for Use *(Describe)*

The SYNFIX Evolution Spacer System is a stand-alone anterior interbody fusion device indicated for use in patients with degenerative disc disease (DDD) at one or two contiguous levels from L2 to S1. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. DDD patients may also have up to Grade I spondylolisthesis at the involved level(s). These patients should be skeletally mature and have had six months of non-operative treatment.

Additionally, the SYNFIX Evolution Spacer can be used in patients diagnosed with spinal deformities as an adjunct to fusion with DePuy Synthes Spine supplemental internal fixation products (e.g. pedicle screw system) for use in the lumbar spine in addition to integrated screws. These patients should be skeletally mature and have undergone six months of nonoperative treatment prior to surgery.

These implants are used to facilitate fusion in the lumbar spine using autogenous bone and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft.

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.<br>325 Paramount Drive<br>Raynham, MA 02767 |
| **Contact Person** | Eugene Bang<br>Regulatory Affairs Associate<br>Telephone: (508) 977-3966<br>Fax: (508) 828-3797 |
| **Date Prepared** | October 31, 2016 |
| **Trade Name** | T-PAL Spacer System<br>T-PAL Titanium Spacer System<br>SYNFIX Evolution System |
| **Device Class** | T-PAL and T-PAL Titanium Spacer Systems – Class II<br>SYNFIX Evolution System – Class II |
| **Product Code** | T-PAL and T-PAL Titanium Spacer System – MAX<br>SYNFIX Evolution System – OVD |
| **Common Name** | T-PAL and T-PAL Titanium System – Intervertebral Fusion Device With Bone Graft, Lumbar<br>SYNFIX Evolution System - Intervertebral Fusion Device With Integrated Fixation, Lumbar |
| **Classification Name** | T-PAL and T-PAL Titanium System - Intervertebral Body Fusion Device, 21 CFR 888.3080<br>SYNFIX Evolution System - Intervertebral Body Fusion Device, 21 CFR 888.3080 |
| **Primary Predicate** | SYNFIX Evolution System – K150673 |
| **Additional Predicate** | DePuy Spine Concorde Bullet System - K151773<br>NuVasive Interfixated Interbody System - K160051<br>T-PAL Spacer System - K100089<br>T-PAL Titanium Spacer System - K151276 |

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| **Device Description** | T-PAL and T-PAL Titanium Spacer System<br>The T-PAL Spacer is a radiolucent interbody fusion device used in conjunction with supplemental internal fixation to provide structural stability in skeletally mature individuals. The T-PAL Spacer is available in various heights and geometries to best accommodate individualsô pathology and anatomical conditions. The components of this device are manufactured from a radiolucent polymer and titanium alloy. |
| | SYNFIX Evolution System<br>The SYNFIX Evolution is a combination radiolucent and radiopaque stand-alone anterior lumbar interbody device designed to be inserted within the intervertebral disc space in order to provide structural stability in skeletally mature individuals. The SYNFIX Evolution is available as assembled components in various heights and geometries to suit individual pathology and anatomical conditions. The components of this device are manufactured from a radiolucent polymer, titanium alloy and tantalum. |
| **Indications for Use** | T-PAL Spacer System<br><br>The T-PAL Spacer System is indicated for use as an intervertebral body fusion device in skeletally mature patients with degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies) at one or two contiguous levels of the lumbar spine (L2-S1). Additionally, the T-PAL Spacer System can be used in patients diagnosed with spinal deformities as an adjunct to fusion. These patients should be skeletally mature and have undergone six months of non-operative treatment prior to surgery. These implants are used to facilitate fusion in the lumbar spine using autogenous bone and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft. When used as an interbody fusion device these implants are intended for use with supplemental internal fixation systems. |
| | T-PAL Titanium Spacer System<br><br>The T-PAL Titanium Spacer System is indicated for use as an intervertebral body fusion device in skeletally mature patients with degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies) at one or two contiguous levels of the lumbar spine (L2-S1). Additionally, the T-PAL Titanium Spacer System can be used in patients diagnosed with spinal deformities as an adjunct to fusion. These patients should be skeletally mature and have undergone six months of non-operative treatment prior to surgery. These implants are used to facilitate fusion in the lumbar spine using autogenous bone and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft. When used as an interbody fusion device these implants are intended for use with supplemental internal fixation systems. |

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| | SYNFIX Evolution System<br><br>The SYNFIX Evolution Spacer System is a stand-alone anterior interbody fusion device indicated for use in patients with degenerative disc disease (DDD) at one or two contiguous levels from L2 to S1. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. DDD patients may also have up to Grade I spondylolisthesis at the involved level(s). These patients should be skeletally mature and have had six months of non-operative treatment.<br><br>Additionally, the SYNFIX Evolution Spacer can be used in patients diagnosed with spinal deformities as an adjunct to fusion with DePuy Synthes Spine supplemental internal fixation products (e.g. pedicle screw system) for use in the lumbar spine in addition to integrated screws. These patients should be skeletally mature and have undergone six months of non-operative treatment prior to surgery.<br><br>These implants are used to facilitate fusion in the lumbar spine using autogenous bone and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft. |
| **Materials** | The materials of the subject devices remain unchanged from the currently marketed predicate devices. The devices are manufactured from PEEK OPTIMA (per ASTM F2026), tantalum (per ASTM F560), and Ti-6Al-7Nb (per ISO 5832, ASTM F1295). |
| **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. |
| **Summary of the Performance Data** | A literature analysis of published clinical data is provided to support the modified Indications for Use. The clinical and radiographic outcomes demonstrate that lumbar interbody fusion devices similar to the subject devices are as safe and effective as the predicate devices for the modified Indications for Use. No additional testing was required as there were no changes to the technological characteristics of the subject devices. |
| **Conclusion** | The Substantial Equivalence Justification provided in the submission demonstrates that the devices are as safe and effective as the predicate devices because the intended use and technological characteristics remain unchanged.. |