JAN - 6 2014

510(k) Summary

510(k) Summary – SYNFIX Lateral	
Name of Firm:	DePuy Synthes Spine 1302 Wrights Lane East West Chester, PA 19380
510(k) Contact:	Monika McDole-Russell Regulatory Affairs Specialist Telephone: 610-719-5448 Facsimile: 484-356-9682 Email: mcdole-russell.monika@synthes.com
Date Prepared:	January 3, 2014
Trade Name(s):	DePuy Synthes SYNFIX Lateral
Classification:	21 CFR 888.3080 – Intervertebral Body Fusion Device Class II (special controls) Orthopaedic and Rehabilitation Devices Panel (87) Product Code OVD (Intervertebral Fusion Device with Integrated Fixation, Lumbar)
Predicates:	Synthes SynFix-LR Spacer (K072253) Zimmer Spine BAK Vista Interbody Fusion Cage (P950002 S014) Medtronic SOVEREIGN (K121982) Globus Medical InterContinental (K103382) DePuy Synthes Falcon Spacer (K123180)
Device Description(s):	The DePuy Synthes SYNFIX Lateral is a combination radiolucent and radiopaque intervertebral body fusion device. Four screws are inserted through the laterally located plate into the adjacent vertebral bodies. The screws lock securely to the plate using a conical thread locking mechanism. The DePuy Synthes SYNFIX Lateral is available in various heights and geometries to suit individual pathology and anatomical conditions.
Intended Use/ Indications for Use:	The SYNFIX Lateral is a stand-alone lateral lumbar interbody fusion device indicated for use in patients with degenerative disc disease (DDD) at one or two contiguous levels from L2 to L5. The interior of the SYNFIX Lateral spacer component should be packed with autogenous bone graft (i.e. autograft); all four screws must be used when implanting this device. 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.

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Comparison of the device to predicate device(s):	The DePuy Synthes SYNFIX Lateral Spacer is substantially equivalent to the predicates in design, function, performance, material, and intended use.
Performance Data (Non-Clinical and/or Clinical):	*Non-Clinical Performance and Conclusions:* DePuy Synthes conducted the following bench testing (as recommended within FDA Guidances and in accordance with ASTM F2077-11 and ASTM F2267-04): Static Axial Compression; Dynamic Axial Compression; Static Compression Shear; Dynamic Compression Shear; Expulsion; Subsidence. Cadaveric studies were conducted to evaluate performance in flexion/extension and lateral bending. The conclusions drawn from testing demonstrate that the DePuy Synthes SYNFIX Lateral is substantially equivalent in performance to predicate devices. In addition, the safety and compatibility of SYNFIX Lateral implants in an MR environment was established (as recommended with FDA Guidance and in accordance with the ASTM F2052, ASTM F2213, ASTM F2182 and ASTM F2119). *Clinical Performance and Conclusions:* Clinical data and conclusions were not needed for this device.

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 6, 2014

Depuy Synthes Spine
Ms. Monika McDole-Russell
Regulatory Affairs Specialist
1302 Wrights Lane East
West Chester, Pennsylvania 19380

Re: K131276
Trade/Device Name: DePuy Synthes SYNFIX Lateral
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: OVD
Dated: November 26, 2013
Received: November 27, 2013

Dear Ms. McDole-Russell:

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

Enclosure

Indications for Use Statement

510(k) Number(s): K 131276
(if known)

Device Name: DePuy Synthes SYNFIX Lateral

The SYNFIX Lateral is a stand-alone lateral lumbar interbody fusion device indicated for use in patients with degenerative disc disease (DDD) at one or two contiguous levels from L2 to L5. The interior of the SYNFIX Lateral spacer component should be packed with autogenous bone graft (i.e. autograft); all four screws must be used when implanting this device.

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.

Anton E. Dmitriev, PhD
Division of Orthopedic Devices