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

August 21, 2015

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

Re: K150673
Trade/Device Name: SYNFIX® Evolution Secured Spacer System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: OVD
Dated: July 31, 2015
Received: August 3, 2015

Dear Mr. 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" (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

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)*
K150673

Device Name
SYNFIX® Evolution Secured Spacer System

Indications for Use *(Describe)*

The SYNFIX Evolution Secured 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. These DDD patients may also have up to Grade I spondylolisthesis at the involved level(s). The interior of the spacer component of the SYNFIX Evolution can be packed with 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.

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.

510(k) Summary

Submitter:	Synthes USA Products, LLC. 325 Paramount Drive Raynham, MA 02767
Contact Person:	Eugene Bang Regulatory Affairs Associate Telephone: (508) 977-3966 Fax: (508) 828-3797
Date Prepared:	March 13, 2015
Trade Name:	SYNFIX® Evolution Secured Spacer System
Device Class:	Class II
Product Code:	OVD
Common Name:	Intervertebral Fusion Device With Integrated Fixation, Lumbar
Classification Name:	Intervertebral Body Fusion Device
Regulation Number:	21 CFR 888.3080
Classification Panel:	Orthopaedic and Rehabilitation Devices Panel (87)
Primary Predicate:	Synthes SYNFIX-LR (K072253)
Additional Predicates:	Synthes Zero-P (K072981) Synthes SYNCAGE Evolution (K122639) Synthes SYNFIX Lateral (K131276) Medtronic Sovereign (K121982) Centinel Spine Midline II (K141942)
Device Description:	The SYNFIX Evolution Secured Spacer System is a combination radiolucent and radiopaque intervertebral body fusion device. Four screws are inserted through the anteriorly-located plate into the adjacent vertebral bodies. The screws lock securely to the plate using a tapered-thread locking mechanism. The SYNFIX Evolution Secured Spacer System is available as assembled components in various heights and geometries to suit individual pathology and anatomical conditions.

Indications:

The SYNFIX Evolution Secured 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. These patients may also have up to Grade I spondylolisthesis at the involved level(s). The interior of the spacer component of the SYNFIX Evolution can be packed with 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.

Materials:

The spacer component is manufactured from medical grade PEEK OPTIMA LT-1 (ASTM F2026) with tantalum alloy markers (ASTM F 560). The plate and screws are manufactured from Ti-6Al-7Nb (ISO 5832).

Comparison to Predicate Device:

The substantial equivalence of the subject device to the predicates identified above is based upon the equivalence of intended use, design (fundamental scientific technology), materials, performance, sterility, and biocompatibility.

Performance Data:

Performance data in the form of Finite Element Analysis and mechanical testing per ASTM F2077 (compression, compression shear) was performed to provide data to support a substantial equivalence determination. The Finite Element Analysis and mechanical testing was performed to characterize the properties and functionality of the system, as well as to allow comparison with established acceptance criteria.

Clinical Test Summary:

No clinical data was necessary to demonstrate substantial equivalence, nor safety and effectiveness of this system.

Conclusion:

Based on the predicate comparison of intended use, indications, technological characteristics, and device performance, the SYNFIX Evolution Secured Spacer System has demonstrated substantial equivalence to the identified predicate device systems.