K122211

SYNTHES®
Spine

DEC 17 2012

5 510(k) Summary

510(k) Summary	
Name of Firm:	DePuy Synthes Spine 1302 Wrights Lane East West Chester, PA 19380
510(k) Contact:	Hemal Mehta Regulatory Affairs Specialist Telephone: 610-719-5424 Facsimile: 610-719-5102 Email: mehta.hemal@synthes.com
Date Prepared:	December 14, 2012
Trade Name:	Synthes Navigable Pedicle Preparation Instruments
Classification:	Sec. 882.4560 Class II Orthopaedic Product Code: OLO, HAW
Predicate Devices:	K070106 BrainLab VectorVision Fluoro3D System K050438 Medtronic StealthStation K003111 Stryker SpineMap
Device Description:	The Navigable Pedicle Preparation Instruments are manual surgical instruments which are designed to interface with already-cleared surgical navigation systems. Instruments in this system may be pre-calibrated to already-cleared surgical navigation systems, or may be manually calibrated to already-cleared surgical navigation systems using manufacturers' instructions. These instruments are intended to be used in spine applications to perform general manual functions within the orthopaedic surgical environment.
Intended Use/ Indications for Use:	The Synthes Navigable Pedicle Preparation Instruments are intended to assist the surgeon in precisely locating anatomical structures in either open, minimally invasive, or percutaneous procedures. These are indicated for use in surgical spinal procedures, in which the use of stereotactic surgery may be appropriate, and where reference to a rigid anatomical structure, such as the pelvis or a vertebra can be identified relative to the acquired image (CT, MR, 2D fluoroscopic image or 3D fluoroscopic image reconstruction) and/or an image data based model of the anatomy. These procedures include but are not limited to spinal fusion.

510(k) Summary	
Comparison of the device to predicate device(s):	The design features, materials, and indications for use of the subject Synthes Navigable Pedicle Preparation Instruments are substantially equivalent to the predicate devices identified.
Performance Data (Non-Clinical and/or Clinical):	Synthes conducted validation activities including usability testing. The Navigable Pedicle Preparation Instruments met the performance requirements, providing assurance of device performance for their intended use. No safety or effectiveness issues were raised by the performance testing. Clinical data was not needed for the Navigable Pedicle Preparation Instruments.

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

Synthes Spine
% Mr. Hemal Mehta
Regulatory Affairs Specialist
1302 Wrights Lane East
West Chester, Pennsylvania 19380

December 17, 2012

Re: K122211
Trade/Device Name: Synthes Navigable Pedicle Preparation Instruments
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic instrument
Regulatory Class: II
Product Code: OLO, HAW
Dated: October 23, 2012
Received: October 24, 2012

Dear Ms. Guerin:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Peter D. Rumm -S

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

Enclosure

SYNTHES®
Spine

4 Indications for Use Statement

510(k) Number: K122211
(if known)

Device Name: Synthes Navigable Pedicle Preparation Instruments

Indications for Use:

The Synthes Navigable Pedicle Preparation Instruments are intended to assist the surgeon in precisely locating anatomical structures in either open, minimally invasive, or percutaneous procedures. These are indicated for use in surgical spinal procedures, in which the use of stereotactic surgery may be appropriate, and where reference to a rigid anatomical structure, such as the pelvis or a vertebra can be identified relative to the acquired image (CT, MR, 2D fluoroscopic image or 3D fluoroscopic image reconstruction) and/or an image data based model of the anatomy. These procedures include but are not limited to spinal fusion.

Prescription Use X (21 CFR 801 Subpart D)	AND / OR	Over-the-Counter Use (21 CFR 801 Subpart C).

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R.P. Ogden 2012.12.14 14:23:06 -05'00'

(Division Sign-off)
Division of Surgical Devices
510(k) Number____K122211___