FEB 18 2011

510(k) Summary

K103558

510(k) Summary	
Name of Firm:	Synthes Spine 1302 Wrights Lane East West Chester, PA 19380
510(k) Contact:	Heather Guerin Regulatory Affairs Specialist Telephone: 610-719-5432 Facsimile: 610-719-5102 Email: guerin.heather@synthes.com
Date Prepared:	February 3, 2011
Trade Name:	Synthes Scout Vessel Guard
Classification:	870.3470 Class II Cardiovascular Devices Panel Product Code OMR
Predicate Devices:	Gore Preclude® Vessel Guard, K061727 SpineMedica Paradis Vaso Shield™, K090022, K093551 Replication Medical EnGuard™ Vessel Guard, K082782
Device Description:	The Scout Vessel Guard is a permanent, non-absorbable membrane made of hydrogel. It is packaged wet in phosphate buffered saline (PBS). This device is designed to be placed between the anterior spine and proximate vessels during anterior lumbar surgery, and is flexible, allowing it to contour to the anatomy. The Scout Vessel Guard can be affixed to bone and/or soft tissue.
Intended Use/ Indications for Use:	The Scout Vessel Guard is indicated as a cover for vessels during anterior vertebral surgery.
Comparison of the device to predicate device(s):	The design features, material, and indications for use of the subject Scout Vessel Guard are substantially equivalent to the predicate devices identified.
Performance Data (Non-Clinical and/or Clinical):	Synthes conducted the following verification and validation activities: suture retention, tensile testing, pore size analysis, freeze testing, material stability testing, usability (cadaver lab) testing, and biocompatibility in accordance with ISO 10993. The Synthes Scout Vessel Guard met the performance requirements, providing reasonable assurance of device performance for its intended use and supporting substantial equivalence. Clinical data was not needed for this device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

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Synthes Spine
c/o Heather Guerin, Ph.D., P.E.
Regulatory Affairs Specialist
1302 Wrights Lane East
West Chester, PA 19380

Re: K103558
Synthes Scout Vessel Guard
Regulation Number: 870.3470
Regulation Name: Intracardiac patch or pledget
Regulatory Class: II
Product Code: OMR
Dated: December 1, 2010
Received: December 2, 2010

Dear Dr. 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). You may, therefore, market the device, subject to the general controls provisions of the Act and the limitations described below. 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.

The Office of Device Evaluation has determined that there is a reasonable likelihood that this device will be used for an intended use not identified in the proposed labeling and that such use could cause harm. Therefore, in accordance with Section 513(i)(1)(E) of the Act, the following limitation must appear in the Warnings section of the device's labeling:

> The safety and effectiveness of this device for reducing the incidence, severity, and extent of post-operative adhesion formation have not been established.

Furthermore, the indication for use as a cover during anterior vertebral surgery must be prominently displayed in all labeling, including pouch box, and carton labels, instructions for use, and other promotional materials, in close proximity to the trade name, of a similar point size, and in bold print.

Please note that the above labeling limitations are required by Section 513(i)(1)(E) of the Act. Therefore, a new 510(k) is required before these limitations are modified in any way or removed from the device's labeling.

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

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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. 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 contact the CDRH/Office of Surveillance and Biometrics/Division of Postmarket Surveillance at (301) 796-6926. For more information regarding the reporting of adverse events, please go to http://www.fda.gov/cdrh/mdr/.

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/cdrh/industry/support/index.html.

Sincerely yours,

Christy Foreman

Christy Foreman
Acting Director
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K103558

Device Name: Synthes Scout Vessel Guard

Indications For Use: The Scout Vessel Guard is indicated as a cover for vessels during anterior vertebral surgery.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K103558