2 510(k) Summary

Name of Firm:	Synthes Spine 1302 Wrights Lane East West Chester, PA 19380
510(k) Contact:	Susan Lewandowski Manager, Spine Regulatory Affairs Telephone: 610-719-5712 Facsimile: 610-719-5102 Email: lewandowski.susan@synthes.com
Date Prepared:	September 15, 2008
Trade Name:	NGarde System
Common Name:	Pedicle Screw System
Classification:	21 CFR 888.3070 – Posterior metal/polymer spinal system Class II Orthopaedic and Rehabilitation Devices Panel Product Code NQP
Predicate Device:	NFix II Pedicle Screw System (N Spine, Inc. K061774) Pangea Pedicle Screw System (Synthes, Inc. K052123) Click'X Pedicle Screw System (Synthes, Inc. K992739)
Device Description:	The NGarde System is a posterior, non-cervical instrumentation system consisting of both pedicle screws and connecting rods. Screws are of polyaxial top-loading design, are composed of titanium 6Al-4V alloy or titanium 6Al-7Nb, and are available in a range of diameters and lengths to accommodate physiological requirements. The rods are composed of titanium 6Al04V alloy and synthetic polycarbonate urethane (PCU) polymer, are 6.0mm in diameter, and are also available in a range of lengths, from 40mm to 200mm. The modification which is the subject of this Special 510(k) consists of the addition to the NGarde System of two alternate pedicle screws, offered in commercial distribution, which may be used at the physician's discretion as an alternative to the NGarde Systems screws. These alternative pedicle screws are similar and comparable to the NGarde screws and are available in a range of diameters and lengths.

Intended Use / Indications for Use:	The subject device is indicated for use as follows: When used as a pedicle screw fixation system in skeletally mature patients, the NGarde System is intended to provide immobilization and stabilization of spinal segments as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the lumbar and sacral spine: degenerative spondylolisthesis with objective evidence of neurological impairment and kyphosis. In addition, when used as a pedicle screw fixation system, the NGarde System is indicated in patients: • Who are receiving fusions with autogenous graft only; • Who are having the device fixed or attached to the lumbar or sacral spine; • Who are having the device removed after the development of a solid fusion mass.
Comparison of the technological characteristics of the device to the predicate device:	In accordance with the agency guideline entitled The New 510(k) Paradigm – Alternate Approaches to Demonstrating Substantial Equivalence in Premarket Notifications, issued March 1998, it has been established, through rigorous design control and risk analysis procedures, that the subject Modification of the NGarde System is substantially equivalent to the predicate systems.
Performance Data (Nonclinical and/or Clinical)	*Non-Clinical Performance and Conclusions:* Such verification and validation tests were identified as appropriate to address the results of a risk analysis for the subject Modification were completed, and met all acceptance criteria. *Clinical Performance:* No clinical testing was conducted to support this submission. *Conclusions:* The results of all design, risk analysis, and verification and validation activities supported the substantial equivalence of the Modified System to the predicate systems.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Synthes Spine Company, LP
% Ms. Susan Lewandowski
Manager, Spine Regulatory Affairs
1302 Wrights Lane East
West Chester, Pennsylvania 19380

DEC 12 2008

Re: K072685
Trade/Device Name: NGarde System
Regulation Number: 21 CFR 888.3070
Regulation Name: Posterior Metal/Polymer Spinal System
Regulatory Class: Class II
Product Code: NQP
Dated: September 19, 2007
Received: September 21, 2007

Dear Ms. Lewandowski:

This letter corrects our substantially equivalent letter of October 19, 2007.

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 Warning section of the device's labeling:

"The safety and effectiveness of this device for use in the treatment of spinal stabilization for non-fusion have not been established."

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); 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 information about the application of other labeling requirements to your device (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Donna-Bea Tillman, Ph.D., M.P.A.
Director
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

SYNTHES®
Spine

1 Indications for Use Statement

Indications for Use Statement

510(k) Number: K072685

Device Name: NGarde System

Indications: When used as a pedicle screw fixation system in skeletally mature patients, the NGarde System is intended to provide immobilization and stabilization of spinal segments as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the lumbar and sacral spine: degenerative spondylolisthesis with objective evidence of neurological impairment, and kyphosis.

In addition, when used as a pedicle screw fixation system, the NGarde System is indicated in patients:

- Who are receiving fusions with autogenous graft only;
- Who are having the device fixed or attached to the lumbar or sacral spine;
- Who are having the device removed after the development of a solid fusion mass.

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)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K072685