## 510(K) SUMMARY

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MAR 2 5 2011

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| **Submitter's name :** | **Syntec Scientific Corporation** |
| **Address :** | **2, Kung San Rd,**<br>**Chuan Shing Industrial Zone,**<br>**Shen Kang,**<br>**Chang Hua,**<br>**Taiwan**<br>**Tel : 886-4-7987099**<br>**Fax: 886-4-7987077** |
| **Contact person :** | Carol Chang |
| **Name of the device :** | **Syntec OS Spinal Fixation System** |
| **Trade or proprietary name :** | **Syntec OS** |
| **Common name:** | **Spinal Fixation System** |
| **Classification name :** | **Non-cervical, Pedicle System** |
| **Produce Code :** | **MNH, MNI, NKB** |
| **Regulation Number :** | **21 CFR 888.3070** |
| **Class :** | **III** |
| **Predicate device:** | **CD HORIZON Spinal system (K091442) / Medtronic Sofamor Danek USA** |
| **Preparation date:** | **January 10, 2011** |

**Description of the Device:**

The Syntec OS Spinal Fixation System is manufactured from titanium alloy (as per ASTM F136) and is designed with various sizes to provide stabilization as an adjunct to spinal fusion surgery. Surgeons can use our top loading technique through the screws and rods to fix the components into a U-shaped opening

**Indications for Use:**

Syntec OS Spinal Fixation System is intended to provide immobilization and stabilization of spinal segments in the thoracic, lumbar, and sacral spine as an adjunct to fusion in the treatment of the following:

- Degenerative disc disease
- Spondylolisthesis
- Trauma (i.e., fracture or dislocation)

- Spinal stenosis
- Deformities or curvatures (i.e., scoliosis, kyphosis, and/or lordosis)
- Tumor
- Pseudoarthrosis
- Failed previous fusion

**Performance Data**

Performance testing and engineering analysis was performed and submitted to characterize the modified components of the system. Static and dynamic axial compression and static torsion tests in accordance with ASTM F1717 were performed on the modified and predicate systems. The modified device functioned as intended and the observed test results demonstrate substantial equivalence to the predicate device.

**Conclusion:**

The Syntec OS Spinal Fixation System uses established surgical techniques and does not introduce new concerns regarding safety and effectiveness. Therefore, the system may be considered substantially equivalent to the predicate 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

MAR 25 2011

Syntec Scientific Corporation
% Ms. Carol Chang
Regulatory Affairs Specialist
2 Kung San Road, Chuan Shing Industrial Zone,
Shen Kang, Chang Hua, Taiwan 509

Re: K101971
Trade Name: Syntec OS Spinal Fixation System
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle screw spinal system
Regulatory Class: Class III
Product Code: NKB, MNI, MNH
Dated: March 10, 2011
Received: March 14, 2011

Dear Ms. Chang:

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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,

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

Enclosure

# INDICATION FOR USE

## Indications for Use

**510(k) Number (if known):** K101971
**Device Name: Syntec OS Spinal Fixation System**
**Indications for Use:**

Syntec OS Spinal Fixation System is intended to provide immobilization and stabilization of spinal segments in the thoracic, lumbar, and sacral spine as an adjunct to fusion in the treatment of the following:

- Degenerative disc disease
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- Tumor
- Pseudoarthrosis
- Failed previous fusion

**Prescription Use _____X_____ AND/OR Over-The-Counter Use___**
**( Part 21 CFR 801 Subpart D)** **(21 CFR 801 Subpart C)**

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

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**Concurrence of CDRH, Office of Device Evaluation (ODE)**

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices



510(k) Number K101971