

Special 510(k) Summary
for the Scient'x Spinal System

K062912
Page 1 of 1

This safety and effectiveness summary for the Scient'x Spinal System is provided as required per Section 513(i)(3) of the Food, Drug and Cosmetic Act.

Date Prepared: January 9, 2007

1. Submitter:

Scient'x
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78284 Guyancourt
FRANCE

Contact Person:

J.D. Webb
The OrthoMedix Group, Inc.
1001 Oakwood Blvd
Round Rock, TX 78681
Telephone: 512-388-0199

FEB - 5 2007

2. Trade name:

Scient'x Spinal System

Common Name:

posterior pedicle screw system

Classification Name:

Pedicle screw spinal system
21 CFR 888.3070
MNI/MNH

3. Predicate or legally marketed devices which are substantially equivalent:

- Scient'x previously cleared devices:
 - Polyaxial hemispherical screw - K051063
 - Polyaxial U Screws - K013444
 - U Screw - K990118
 - Hemispherical headed screw - K990118
 - MX Polyaxial screw - K043001
 - MX Monoaxial - K042964
- LTD Polyaxial Screw – K062785 (US Spine)

4. Description of the device:

The Scient'x Spinal System consists of monoaxial pedicle screws, rigid rods and crosslink members, semi-rigid rods, polyaxial screws, cross link and closed and open screws. It can be used for single or multiple level fixations. The modifications included in this submission is the addition of Polyaxial LP Screws, and additional sizes of Polyaxial TTL U Screws, Polyaxial TTL High U-screw, Monoaxial TTL U Screws, Polyaxial Hemispherical Screws, MX Polyaxial Screws, MX Monoaxial Screws – Closed and MX Monoaxial Screws - Open.

Materials:

Ti6Al4V alloy, conforming to ASTM F136 and ISO 5832-3

5. Intended Use:

The Scient'x Spinal System is a posterior, noncervical pedicle and non-pedicle system intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of thoracic, lumbar and sacral spine: degenerative spondylolisthesis with objective evidence of neurological impairment, fracture, dislocation, kyphosis, spinal tumor, and failed previous fusion (pseudoarthrosis).

6. Comparison of the technological characteristics of the device to predicate and legally marketed devices:

The Scient'x pedicle screws included in this submission are modifications to previous Scient'x pedicle screws and a recently cleared US Spine screw. All have the same indications and material, and similar designs. Changes are confined to modification of screw diameter and/or polyaxial mechanism.

7. Summary of Nonclinical Tests

Testing was undertaken to determine the mechanical properties of the pedicle screw systems. Testing was performed following the protocol of ASTM F1717 "Standard Test Methods for Spinal Implant Constructs in a Vertebrectomy Model."



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Scient'x
c/o Mr. J.D. Webb
The Orthomedix Group, Incorporated
1101 Oakwood Boulevard
Round Rock, Texas 78681

FEE - 2006

Re: K062912
Trade/Device Name: Scient'x Spinal System
Regulation Number: 21 CFR §888.3070
Regulation Name: Pedicle Screw Spinal System
Regulatory Class: Class II
Product Code: MNI, MNH, KWP, KWQ
Dated: September 22, 2006
Received: September 27, 2006

Dear Mr. Webb:

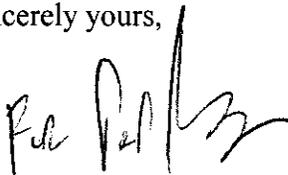
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 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) 276-0120. 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,



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

Enclosure

Indications for Use

510(k) Number (if known): K062912

Device Name: Scient'x Spinal System

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- Degenerative spondylolisthesis with objective evidence of neurological impairment,
- Fracture,
- Dislocation,
- Kyphosis,
- Spinal tumor, and
- Failed previous fusion (pseudoarthrosis).

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 OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Barbara Buchheit for NXM
 (Division Sign-Off)
 Division of General, Restorative,
 and Neurological Devices

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