K071261

510(k) Summary

APR 17 2008

Contact: John Sanders
Scient'x USA, Inc.
1015 Maitland Center Commons, Suite 106A
Maitland, FL 32751
407.571.2550

Device Trade Name: ISOBAR Spinal System

Manufacturer: Scient'x
Batiment Calypso Parc Ariane 3
78284 Guyancourt, France

Classification: 21 CFR §888.3070; Pedicle screw spinal system
21 CFR §888.3050; Spinal interlaminal fixation orthosis

Class: II

Product Code: KWP, MNH, MNI, NQP

Indications For Use:
The ISOBAR Spinal System is 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; scoliosis; kyphosis; spinal tumor; and failed previous fusion.

As a pedicle screw system, the ISOBAR Spinal System is intended for the treatment of severe spondylolisthesis (Grade 3 and 4) of the L5-S1 vertebrae in skeletally mature patients receiving fusion by autogenous bone graft having implants attached to the lumbar and sacral spine (L3 to sacrum) with removal of the implants after the attainment of solid fusion.

The Semi-Rigid Rod and Dual Dampener Rod should only be used at levels (one and two levels, respectively) that will be fused.

Device Description:
The ISOBAR Spinal System consists of pedicle screws, rigid rods and crosslink members (K990118, K013444, K020245, K031290 and K051063), semi-rigid rods (K991326) and hooks (K013440 & 013447). The Isobar Semi-rigid Dual Dampener Rod is an addition to the ISOBAR Spinal System family. The semi-rigid rod allows a very small amount of compression, torsion and bending. The components in this submission are fabricated

from Ti6Al4V alloy, conforming to ASTM F136 and ISO 5832-3, which is known to be biocompatible.

Predicate Device(s):
The ISOBAR Spinal System was shown to be substantially equivalent to previously cleared devices and has the same indications for use, design, function, and materials.

Performance Standards:
Testing performed indicates the ISOBAR Spinal System is substantially equivalent to predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 17 2008

Scient'x USA, Inc.
% Mr. John Sanders
Quality Assurance Regulatory Affairs Manager
1015 Maitland Center Commons
Suite 106A
Maitland, FL 32751

Re: K071261
Trade/Device Name: ISOBAR Spinal System
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle screw spinal system
Regulatory Class: II
Product Code: NQP, MNI, MNH, KWP
Dated: April 4, 2008
Received: April 7, 2008

Dear Mr. Sanders:

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 the indication of spinal stabilization without 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 toll-free number (800) 638-2041 or (240) 276-3150 or the 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

K071261

Indications for Use

510(k) Number (if known): K071261

Device Name: ISOBAR Spinal System

Indications for Use: The ISOBAR Spinal System is 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; scoliosis; kyphosis; spinal tumor; and failed previous fusion.

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Prescription Use ___√___ (Part 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 OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R P Ogden for mxn

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

510(k) Number K071261