JUL - 1 2004

510(k) SUMMARY

SUBMITTED BY

Wendy Spielberger
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May 28, 2004

This summary of 510(k) substantial equivalence information is being submitted in accordance with the requirements of 21 CFR §807.92.

CLASSIFICATION, COMMON OR USUAL NAME, DEVICE NAME

Classification Name: Spinal Intervertebral Body Fixation Orthosis
Common/Usual Name: Anterior and Posterior Spinal Implants
Product Classification: Class II
Proprietary Name: Synergy™ Spinal System

PREDICATE DEVICE

Predicate device information is included in this premarket notification.

INDICATIONS-FOR-USE

The Synergy Spinal System implants are intended to be used as a temporary construct that assists normal healing and are not intended to replace normal body structures. They are intended to stabilize the spinal operative site during fusion procedures and should be removed after fusion.

The implants are attached to the spine posteriorly by means of hooks and/or screws joined with rods and anteriorly by means of vertebral screws joined with rods.

As a pedicle screw system, the Synergy Spinal System is intended only for patients: (a) having severe spondylolisthesis (Grades 3 and 4) of the fifth lumbar-first sacral (L5-S1) vertebral joint; (b) who are receiving fusions using autogenous bone graft only; (c) who are having the screws fixed or attached to the lumbar and sacral spine; and (d) who are having the device removed after the development of a solid fusion mass. The levels of screw fixation are L3 to S1/Ilium.

In addition, the pedicle screw system may also be used 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 the thoracic, lumbar, and sacral spine: degenerative spondylolisthesis with objective evidence of neurologic impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (pseudarthrosis).

As a posterior, non-pedicle, screw and hook system, and an anterolateral, intervertebral body screw system, the specific indications for the Synergy Spinal System are:

1. Degenerative Disc Disease (as defined by chronic back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies).
2. Idiopathic scoliosis.
3. Kyphotic deformities of the spine.
4. Paralytic scoliosis and/or pelvic obliquity.
5. Lordotic deformities of the spine.
6. Neuromuscular scoliosis associated with pelvic obliquity.
7. Vertebral fracture or dislocation.
8. Tumors.
9. Spondylolisthesis.
10. Stenosis.
11. Pseudarthrosis.
12. Unsuccessful previous attempts at spinal fusion.

For posterior, non-pedicle, screw use, the Synergy screws and lateral connectors are intended for sacral/iliac attachment only, and the Synergy hooks and transverse connectors are intended for posterior thoracic and/or lumbar use only. As a whole, the levels of use are T1 to the Sacrum/Ilium.

The Adjustable Length Rod is intended for in situ adjustment after placement of the hooks or screws during spinal fusion surgery.

For anterior use, the recommended levels of attachment are: T10 to L3 for the double rod constructs and T5 to L5 for the single rod constructs. The 4.75 mm diameter rod system can be used in single and double rod constructs while the 6.35 mm diameter rod system is to only be used in single rod constructs. In all cases, instrumentation must be at least 1 cm from any major vessel.

DEVICE DESCRIPTION

The Synergy™ Spinal System components are grouped as follows:

Posterior Application:

1. Integral™ Open, Closed, Angled Closed and Reduction Screws, Variable Locking Screws with Variable Locking Seats and Iliac Screws with Hex Nuts and Set Screws. Caution: Only the Integral™ Open, Closed, Reduction and Variable Locking Screws are intended for pedicle fixation.
2. Open and Closed Spinal Hooks with Sliders, C-rings and Set Screws.
3. Adjustable and Fixed Transverse Connectors with Set Screws.
4. Closed and Axial Rod Connectors with Set Screws.
5. Lateral Connectors with Set Screws.
6. Rods and Adjustable Length Rods and Set Screws.
7. Instruments.
8. Sterilizer case(s).

Anterior Application:

1. Integral™ Open and Closed Screws and Variable Locking Screws with Variable Locking Seats, with Hex Nuts and Set Screws.
2. Vertebral Washers.
3. Fixed Transverse Connectors with Set Screws.

4. Rods.
5. Instruments.
6. Sterilizer case(s).

NOTE: While the Variable Locking Screws and some fasteners (nuts and set screws) are used for both the 6.35mm and 4.75mm rod sizes, the remaining components (except for those connector components that are designed to join the two rod sizes) are designed for specific rod diameters.

NOTE: The Adjustable Length Rod is intended for in situ adjustment after placement of the hooks or screws during spinal fusion surgery.

The Adjustable Length Rod is intended for use as part of either a single or double rod assembly. The Adjustable Length Rod allows for distraction at a central location once the bone anchors have been secured.

COMPARISON TO THE PREDICATE DEVICE

Based on the same indications for use, intended use, similarity in materials of construction and equivalent biomechanical performance, the Synergy Spinal System is considered substantially equivalent to the legally marketed predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL - 1 2004

Wendy Spielberger
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Interpore Cross International
181 Technology Drive
Irvine, California 92618-2402

Re: K041449
Trade/ Device Name: Synergy™ Helical Flange Plug, Seat, and Reduction Seat
Regulation Numbers: 21 CFR 888.3050, 21 CFR 888.3060, 21 CFR 888.3070(b)(1)
Regulation Names: Spinal interlaminal fixation orthosis, Spinal intervertebral body fixation orthosis, Pedicle screw spinal system
Regulatory Class: II
Product Codes: KWP, KWQ, MNH
Dated: May 28, 2004
Received: June 1, 2004

Dear Ms. Spielberger:

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 (301) 594-4659. 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 (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Miriam C. Provost

for Celia M. Witten, Ph.D., M.D.
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): K041449

Device Name: Synergy Helical Flange Plug, Seat, and Reduction Seat

Indications-For-Use:

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7. Vertebral fracture or dislocation.
8. Tumors.
9. Spondylolisthesis.
10. Stenosis.
11. Pseudarthrosis.
12. Unsuccessful previous attempts at spinal fusion.

(continued)

Indications for Use (continued)

510(k) Number (if known): K041449

Device Name: Synergy Helical Flange Plug, Seat, and Reduction Seat

Indications-For-Use (cont'd):

For posterior, non-pedicle, screw use, the Synergy screws and lateral connectors are intended for sacral/iliac attachment only, and the Synergy hooks and transverse connectors are intended for posterior thoracic and/or lumbar use only. As a whole, the levels of use are T1 to the Sacrum/Ilium.

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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)

Miriam C. Provost

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

510(k) Number K041449