3/23/99

K984578

510(k) SUMMARY

SUBMITTED BY

Lynn Rodarti
Manager, Regulatory Affairs
Interpore Cross International
181 Technology Drive
Irvine, California 92618

(949) 453-3200

Date Submitted: December 22, 1998

CLASSIFICATION, COMMON OR USUAL NAME, DEVICE NAME

Classification Name:	Spinal Intervertebral Body Fixation Orthosis Appliance, Fixation, Spinal Interlaminal Spondylolisthesis Spinal Fixation Device System
Common/Usual Name:	Anterior and Posterior Spine Implants, Universal Spine System
Product Classification:	Class II
Proprietary Name:	Synergy™ D2 Spinal Implants

PREDICATE DEVICE

The predicate device is the Interpore Cross International Synergy Interior and Posterior, Stainless Steel and Titanium Spinal Systems.

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

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 having the screws fixed or attached to the lumbar and sacral spine; (c) who are receiving fusions using autogenous bone graft only; 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 discogenic origin with degeneration of the disc confirmed by hitory 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.

For anterior use, the recommended levels of attachment are: T10 – L3 for the double rod constructs and T5 – L5 for the single rod construct. The 4.75 mm diameter rod system can be used in single and double rod constructs while the 6.35mm 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. 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.
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 (nut 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.

COMPARISON TO THE PREDICATE DEVICE

The Interpore Cross Synergy D2 Spinal Implants are technologically substantially equivalent to the predicate devices based on the basic design concept, the use of established well-known materials, feature comparisons, mechanical testing, indications for use, surgical approach, preproduction quality assurance planning and engineering analysis.

DISCUSSION OF NONCLINICAL TESTS

Data regarding the functional performance of the proposed Synergy D2 Spinal Implants has been generated. Testing included unilateral construct fatigue testing in axial compression. The data indicates that the proposed Synergy D2 Spinal Implants meet or exceed all functional requirements and support their suitability for use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 23 1999

Ms. Lynn M. Rodarti
Manager, Regulatory Affairs
Interpore Cross International
181 Technology Drive
Irvine, California 92618-2402

Re: K984578
Trade Name: Synergy™ D2 Spinal Implants
Regulatory Class: II
Product Codes: KWQ, KWP, MNH, and MNI
Dated: December 22, 1998
Received: December 23, 1998

Dear Ms. Rodarti:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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. 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597, or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Celia M. Witten, Ph.D., M.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K984578

Device Name: Synergy™ D2 Spinal Implants

Indications-For-Use:

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(continued)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Off)

eral Restorative Devices

Number K984578

Prescription Use ✓ OR **Over-The-Counter Use**
(PER 21 CFR 801.109)

510(k) Number (if known): K984578

Device Name: Synergy™ D2 Spinal Implants

Indications-For-Use (cont'd):

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Prescription Use X
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K984578