K991526

NOV - 8 1999

510(k) Summary of Safety and Effectiveness

(1)	**Submitter's name:**	Encore Orthopedics, Inc.
	Submitter's address:	9800 Metric Blvd, Austin, TX 78758
	Submitter's telephone number:	(512) 834-6237
	Contact person:	Debbie De Los Santos
	Date summary prepared:	November 5, 1998
(2)	**Trade or proprietary device name:**	ISOBAR Semi-rigid Spinal System
	Common or usual name:	Pedicle screw spinal system
	Classification name:	Class II
(3)	**Legally marketed predicate device:**	ISOBAR Spinal System (K990118)

(4) **Subject device description:**

The ISOBAR Semi-rigid Spinal System consists of pedicle screws, rods, nuts and crosslink members. It can be used for single or multiple level fixation. All components are manufactured from titanium alloy (Ti-6Al-4V) that conforms to ASTM F136.

This system consists of pedicle screws that require rod attachment directly over the top of the screw (U-Line Screws) and a combination of screws and clamps that allow the rod to be offset from the screw (Hemispherical Headed Screws).

(5) **Subject device intended use:**

The ISOBAR Semi-rigid Spinal System is a pedicle screw 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, spinal tumor, and failed previous fusion (pseudarthrosis).

As a pedicle screw system, the ISOBAR Semi-rigid 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 a solid fusion.

(6) **Performance data:**

The Food and Drug Administration have established no performance standards applicable to pedicle screw spinal systems. However, static and fatigue compression testing of the U-Line Screws was performed according to ASTM F1717-96.

(7) **Basis for substantial equivalence:**

The ISOBAR Semi-rigid Spinal System is equivalent to the ISOBAR Spinal System cleared on K990118.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV - 8 1999

Ms. Debbie De Los Santos
Regulatory/Clinical Specialist
Encore Orthopedics, Inc.
9800 Metric Boulevard
Austin, Texas 78758

Re: K991326
ISOBAR Semi-Rigid Spinal System
Regulatory Class: II
Product Codes: MNI and MNH
Dated: August 10, 1999
Received: August 11, 1999

Dear Ms. De Los Santos:

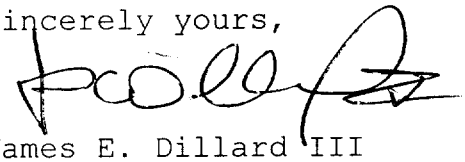
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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 (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,



James E. Dillard III
Acting Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K991326

Device Name: ISOBAR Semi-rigid Spinal System

Indications For Use:

ISOBAR Semi-rigid Spinal System

Indications For Use

The ISOBAR Semi-rigid Spinal System is a pedicle screw 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, spinal tumor, and failed previous fusion (pseudarthrosis).

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K991326

Prescription Use + OR Over-The-Counter Use ____
(per 21 CFR 801.109)

(Optional Format 1-2-96)_