2/24/99

K984251

510(k) Summary

Device: XIA SPINE SYSTEM

Common Name: Spinal Fixation Device
Classification Name: Spinal Interlaminal Fixation Orthosis (888.3050)
Spinal Intervertebral Body Fixation Orthosis
(888.3060)
Pedicle Screw Spinal System (888.7070)
Regulatory Class: Class II
Product Code: 87KWP, 87KWQ, 87MNH and 87MNI

For information contact: Vivian Kelly
Manager, Regulatory Affairs
Howmedica Inc.
359 Veterans Boulevard
Rutherford, NJ 07070
(201) 507-7830
Fax: (201) 507-6870

The XIA Spine System is a spinal fixation device for the noncervical spine. It consists of rods, monoaxial and polyaxial bone screws, different types of hooks, closure screws, axial and parallel rod to rod clamps, lateral connectors and cross link components. The components are manufactured from titanium.

When used as a pedicle screw fixation system, the XIA Spine System is intended for patients: (a) having severe spondylolisthesis (Grades 3 and 4) at the fifth lumbar - first sacral (L5-S1) vertebral joint which is fused; (b) who are receiving fusions using autogenous bone graft only; (c) who are having the device 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. Pedicle screw fixation is limited to L3 to S1 or the ilium.

When used as a pedicle screw fixation system, the XIA Spine System is also 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 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).

When used an anterior screw fixation system or a posterior hook and sacral/iliac screw fixation system, the XIA Spine System is indicated for patients with degenerative disc disease of the thoricic, lumbar, which is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies, spondylolisthesis, fracture, spinal stenosis, spinal deformities such as scoliosis, kyphosis, lordosis, tumor, pseudoarthrosis or revision of failed fusion attempts. When used in the posterior non-pedicle indication the Xia system is indicated for use in the thoracic to sacral spine. When used in the anterior indication the Xia system is indicated for use in the thoracic and lumbar spine.

The substantial equivalence of this device is based on an equivalence in intended use, materials, designs and operational principles to other predicate devices indicated for noncervical spinal fixation. These devices include Howmedica's BWM Spine System, Synthes® Spine's Universal Spinal System (USS) and the MOSS Miami Spinal System by DePuy. Bench testing demonstrates that the device will meet it mechanical functional requirements.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 24 1999

Mr. John F. Dichiara
Director of Regulatory Affairs and Public Policy
Howmedica Osteonics Corporation
359 Veterans Boulevard
Rutherford, New Jersey 07070-2584

Re: K984251
Trade Name: XIA Spine System
Regulatory Class: II
Product Codes: KWP, KWQ, MNH, and MNI
Dated: November 25, 1998
Received: November 27, 1998

Dear Mr. Dichiara:

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

Indications for Use

510(k) Number (if known): K984251

Device Name: XIA SPINE SYSTEM

The XIA Spine System is intended for use in the noncervical spine. When used as a pedicle screw fixation system, the XIA Spine System is intended for patients: (a) having severe spondylolisthesis (Grades 3 and 4) at the fifth lumbar - first sacral (L5-S1) vertebral joint which is fused; (b) who are receiving fusions using autogenous bone graft only; (c) who are having the device 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. Pedicle screw fixation is limited to L3 to S1 or the ilium.

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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)

Prescription Use X OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K984251