510(k) Summary

Showa Ika Kohgyo Co., LTD
510(k) Premarket Notification
MYKRES Spinal System

JUL - 3 2006

ADMINISTRATIVE INFORMATION

Manufacturer Name: Showa Ika Kohgyo Co., LTD.
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Japan

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Official Contact: Kazuya Oribe

Representative/Consultant: Floyd G. Larson
PaxMed International, LLC
11234 El Camino Real, Suite 200
San Diego, CA 92130
Telephone: (858) 792-1235
Fax: (858) 792-1236

DEVICE NAME

Classification Name: Orthosis, Spondylolisthesis Spinal Fixation
Orthosis, Spinal Pedicle Fixation
Orthosis, Spinal Interlaminar Fixation

Trade/Proprietary Name: MYKRES Spinal System

Common Name: Spinal Fixation System

ESTABLISHMENT REGISTRATION NUMBER

The establishment registration number for Showa Ika Kohgyo Co, LTD is 3004589749.

DEVICE CLASSIFICATION

Pedicle screw spinal fixation systems are classified as Class II devices (21 CFR 888.3070). The product code for Orthosis, Spondylolisthesis Spinal Fixation is MNH. The product code for Orthosis, Spinal Pedicle Fixation is MNI. Nonpedicle screw fixation systems are classified as Class II devices (21 CFR 888.3050). The product code for Spinal Interlaminar Fixation Orthosis is KWP. These device classifications are reviewed by the Orthopedic Devices Branch.

INTENDED USE

The MYKRES 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 (pseudarthrosis).

The MYKRES Spinal System is indicated for the treatment of severe spondylolisthesis (Grade 3 and 4) of the L5-S1 vertebra in skeletally mature patients undergoing fusion by autogenous bone grafting having implants attached to the lumbar and sacral spine with removal of implants after the attainment of a solid fusion.

DEVICE DESCRIPTION

The MYKRES Spinal System is an internal fixation device for spinal surgery consisting of rods, screws, hooks and connectors available in various lengths, diameters, and configurations to enable close conformance to patient anatomy. A series of manual instruments (not a subject of this submission) intended to assist in the insertion and placement of the implants is provided in separate trays.

The rods, screws, hooks and connectors of the MYKRES Spinal System are made of Ti-6Al-4V titanium alloy conforming to ASTM F 136.

EQUIVALENCE TO MARKETED PRODUCT

Showa Ika Kohgyo has submitted information to demonstrate that, for the purposes of FDA's regulation of medical devices, the MYKRES Spinal System is substantially equivalent in intended use, materials, designs and operational principles to the following predicate devices:

J.B.S. Spine System with Pedicle Screws (K962757) from J.B.S. (USA), Inc.
SYNERGY Spinal System – Closed VLS (K974749) from Interpore Cross International.
MOSS Miami Spinal System (K955348, K983583, K011182) from DePuy AcroMed, Inc.
OPTIMA Spinal System (K031585) from U&i Corp., America.

Comparison of Technological Characteristics

	Subject Device	Predicate Devices			
	MYKRES Spinal System	J.B.S. Spine System with Pedicle Screws	SYNERGY Spinal System – Closed VLS	MOSS Miami Spinal System	OPTIMA Spinal System
		J.B.S. (USA), Inc.	Interpore Cross International	DePuy AcroMed, Inc.	U&i Corp., America
		K962757	K974749	K955348, K983583, K011182	K031585
Intended Use	Posterior pedicle screw and non-pedicle screw fixation indications.	Posterior pedicle screw and non-pedicle screw fixation indications.	Posterior pedicle screw and non-pedicle screw fixation indications.	Posterior and anterior pedicle screw and non-pedicle screw fixation indications.	Posterior and anterior pedicle screw fixation indications.
Classification	MNH, MNI, KWP	MNH, KWP	MNH, KWP, KWQ	MNH, MNI, KWP, KWQ	MNH, KWQ, MNI
Design	Rods, polyaxial screws, monoaxial screws, hooks, connectors	Rods, polyaxial screws, monoaxial screws, hooks, connectors	Rods, polyaxial screws, monoaxial screws, hooks, connectors	Rods, polyaxial screws, monoaxial screws, hooks, connectors	Rods, polyaxial screws, monoaxial screws, connectors
Materials	Ti-6Al-4V	Ti-6Al-4V	Ti-6Al-4V, CP Ti, Stainless Steel	Ti-6Al-4V, Stainless Steel	Ti-6Al-4V

Bench Testing Data

Showa Ika Kohgyo has submitted data from testing performed in compliance with ASTM F 1717. Static compression, static torsion, and dynamic axial compression bending tests using six samples each of a worst case MYKRES construct demonstrate that the MYKRES Spinal System is substantially equivalent to legally marketed spinal fixation systems and is therefore appropriate for use in spinal fixation as described in the indications above.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL - 3 2006

Showa Ika Kogyo Company, Ltd.
c/o Mr. Floyd Larson
PaxMed International, LLC
11234 El Camino Real, Suite 200
San Diego, CA 92130

Re: K051704
Trade/Device Name: Mykres Spinal System
Regulation Number: 888.3070(b)(1)
Regulation Name: Pedicle Screw Spinal System
Regulatory Class: Class II
Product Code: MNH, MNI, KWP
Dated: June 15, 2006
Received: June 19, 2006

Dear Mr. Larson:

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 (240) 276-0120. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Barbara Mechkowski for

Mark N. Melkerson
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): K051704

Device Name: MYKRES Spinal System

Indications for Use:

The MYKRES 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 (pseudarthrosis).

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Prescription Use X
(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 IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number K051704