510(k) Summary

JUL - 2 2008

SHOWA IKA KOHGYO CO., LTD.
MYKRES Spinal System

ADMINISTRATIVE INFORMATION

Manufacturer Name: SHOWA IKA KOHGYO CO., LTD.
8-7 Haneinishi-Machi
Toyohashi, Aichi 441-8026 Japan
Telephone 81 532-32-1543
Fax 81 532-32-1106

Official Contact: Floyd G. Larson, U.S. Agent

Representative/Consultant: Floyd G. Larson
PaxMed International, LLC
11234 El Camino Real, Suite 200
San Diego, CA 92130
Telephone 1 (858) 792-1235
Fax 1 (858) 792-1236

DEVICE NAME AND CLASSIFICATION

Trade/Proprietary Name: MYKRES Spinal System
Common Name: pedicle screw system
Classification Regulations: Pedicle screw spinal system
(21 CFR 888.3070), Class II
Spinal intervertebral body fixation orthosis
(21 CFR 888.3060), Class II
Spinal interlaminal fixation orthosis
(21 CFR 888.3050), Class II

Product Codes: MNI, MNH, KWQ, KWP

DEVICE CLASSIFICATION PANEL

The Classification Panel for these devices is the Orthopedic and Rehabilitation Devices Panel, and they are reviewed by the Orthopedic Spine 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.

When used as an anterior, noncervical screw fixation system, the MYKRES Spinal System is indicated for patients with degenerative disc disease 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, or failed fusion (pseudarthrosis).

DEVICE DESCRIPTION

The subject of this submission is the addition of new system components to facilitate use of the MYKRES Spinal System for anterior noncervical spinal fixation and the addition of such an indication to the statement of intended use. The MYKRES Spinal System, consisting of rods, screws, hooks, connectors and washers, was cleared under K051704 for posterior noncervical spinal fixation. Three new components are available for use in various combinations with certain components previously cleared for posterior spinal fixation

EQUIVALENCE TO MARKETED PRODUCT

SHOWA IKA KOHGYO CO., Ltd. submits the information in this Premarket Notification to demonstrate that, for the purposes of FDA's regulation of medical devices, the modified MYKRES Spinal System is substantially equivalent in design principles to the MYKRES Spinal System (K051704) cleared for posterior noncervical spinal fixation and is substantially equivalent in indications and design principles to the following devices, each of which has been determined by FDA to be substantially equivalent to preamendment devices: the CD Horizon® Spinal System from Medtronic Sofamor Danek, Inc. (K032265), the Kaneda SR Anterior Spinal System and Anterior Scoliosis System from AcroMed Corp. (K971248, K974757), and the Xia Spine System from Howmedica, Inc. (K984251).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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SHOWA IKA KOHGYO CO., LTD.
% PaxMed International, LLC.
Mr. Floyd G. Larson
U.S. Agent
11234 El Camino Real, Suite 200
San Diego, CA 92130

Re: K071074
Trade/Device Name: MYKRES Spinal System
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle screw spinal system
Regulatory Class: II
Product Code: MNI, MNH, KWP, KWQ
Dated: June 27, 2008
Received: June 30, 2008

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.

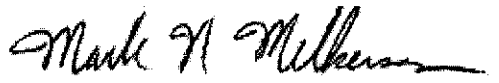
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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,



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): K071074

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 K071074