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K001668
1 of 2

DKM 디·케이·엠 [주]
Dong Kwang Medical Co., Ltd.

SUNGBUK-KU DONGSUN-DONG 1GA 122
DAE-EUN BUILDING 602
SEOUL, SOUTH KOREA
TEL: 82.2.921.6427 / FAX: 82.2.921.6428

SUMMARY OF SAFETY AND EFFECTIVENESS INFORMATION

GLOBAL SPINAL FIXATION SYSTEM

510(k) No.: _____

Date: _____

COMPANY: D.K.M. Co., Ltd
Sung Buk-Ku Dong Sun-Dong 1GA 122
Dae-Eun Building, 602
Seoul, South Korea

CONTACT: Kyung-Tae Kim
Regulatory Affairs / Project Manager
Tel: 82.2.921.6427
Fax: 82.2.921.6428
uaukim@unitel.co.kr

TRADE NAME: Global Spinal Fixation System (GSFS)

COMMON NAME: Pedicle Screw Spinal Fixation System

CLASSIFICATION NAME (CODE): Spinal Pedicle Screw (MNI)
Spondylolisthesis Spinal Fixation Device System (MNH)

CLASSIFICATION: 888.3070

REVIEW PANEL: Orthopedic Devices Branch
Division of General and Restorative Devices

PERFORMANCE STANDARD: D.K.M. Co., Ltd. is not aware of any Special Controls or Performance Standards established for pedicle screw spinal systems under Sections 513 and 514, respectively, of the FD&C Act.

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SUBSTANTIAL EQUIVALENCE

The Global Spinal Fixation System is substantially equivalent to Advanced Spine Technology's Triple-Fix Spinal Fixation System (K992147).

DEVICE DESCRIPTION

The Global Spinal Fixation System (GSFS) is a multiple component system comprised of a variety of single-use, non-sterile devices that allow the surgeon to build a spinal implant construct in order to provide stabilization and promote spinal fusion. The implants are manufactured from titanium alloy, Ti6A14V that conforms to ASTM 136 98 and include pedicle screws, hooks, rods, cross link, and connector. Various sizes of these implants are available. Specialized instrument made from surgical instrument grade stainless steel is available for the application and removal of the GSFS implants.

INDICATIONS FOR USE

The Global Spinal Fixation System is a pedicle screw indicated for the treatment of severe spondylolisthesis (Grade 3 and 4) of the L5-S1 vertebra 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.

The GSFS 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 the thoracic, lumbar and sacral spine: degenerative spondylolisthesis with objective evidence of neurological impairement, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (pseudarthrosis).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 1 9 2000

D.K.M. Company, Limited
c/o Mr. Andrew Paeng
AP Consulting
Post Office Box 3415
St. Louis, Missouri 63143

Re: K001668
Trade Name: Global Spinal Fixation System
Regulatory Class: II
Product Code: MNH, MNI, KWP
Dated: July 31, 2000
Received: August 1, 2000

Dear Mr. Paeng:

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 control provisions of the Act. The general control 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,

for Mark N Melkerson

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

Enclosure

INDICATIONS FOR USE STATEMENT

PMN 510(k) Number: K001668

Device Name

Global Spinal Fixation System

Indications for Use

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In addition, the GSFS 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 the thoracic, lumbar and sacral spine: degenerative spondylolisthesis with objective evidence of neurological impairement, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (pseudarthrosis).

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Mark N. Melkerson

(Division Sign-Off)
Division of General Restorative Devices

510(k) Number K001668

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

(Optional Format 3-10-98)