K042928

FEB 17 2005

[10]

510(k) SUMMARY

The following 510(k) summary is being submitted as required by 21 CFR 807.92(a):

Submission Information:

Contact:	Betty Lim Regulatory Affairs
Sponsor:	U&i Corporation YongHyun-Dong 529-1, Uijungbu Kyonggi-Do, Korea 480-050 Phone: 82-31- 852-0102(ext. 612) Fax: 82-31-852-0108
Date Prepared:	January 3, 2005

Device Identification:

Trade Name:	GLOBAL SPINAL FIXATION SYSTEM™
Common Name:	Pedical Screw Spinal Fixation System
Classification Name:	Spinal Pedical Screw (MNI) per 21 CFR § 888.3070 Spondylolisthesis Spinal Fixation Device System (MNH) per 21 CFR § 888.3070

Substantially Equivalent Predicate Legally Marketed Devices:

The subject GLOBAL SPINAL FIXATION SYSTEM™ is substantially equivalent in function, design, composition, labeling, and intended use to:

GLOBAL SPINAL FIXATION SYSTEM™, Spinal System MNH, MNI – (K001668).
TRIPLE-FIX Spinal Fixation System – KWP, MNH, MNI -- (K992147)
ISOLA Spinal System -- MNH, MNI, KWQ -- (K980485)

The substantial equivalence of this device is based on equivalence in intended use, materials, designs and operational principles to the above listed predicate devices.

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Device Description:

The GLOBAL SPINAL FIXATION SYSTEM™ Spinal System is a multiple component spinal fixation system comprised of 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, Ti-6Al-4V ELI that conforms to ASTM 136 98 and include pedicle screws, set screws, rods, connectors, and transverse (cross) linking mechanism. Various sizes of these implants are available.

Indications for Use:

The GLOBAL SPINAL FIXATION SYSTEM™ is a pedicle screw system 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.

In addition, the GLOBAL SPINAL FIXATION 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 the thoracic, lumbar and sacral spine: degenerative Spondylolisthesis with objective evidence of neurological impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor and failed previous fusion (pseudarthrosis).

Statement of Technological Comparison:

The subject spinal implant system is substantially equivalent to the above listed predicate devices in terms of materials, design, indications for use and operational principles.

Performance Data:

Bench testing as listed in Section XII which was conducted in accordance with ASTM F1717 demonstrates equivalence to the above listed predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 17 2005

Betty Lim
Regulatory Affairs
U&I Corporation
YongHyun-Dong 529-1, Uijungbu
Kyonggi-Do, Korea 480-050

Re: K042928
Trade/Device Name: Global Spinal Fixation System™
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle screw spinal system
Regulatory Class: II
Product Code: MNH, MNI
Dated: January 10, 2005
Received: January 18, 2005

Dear Ms. Lim:

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 (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

for Mark N Milhern

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

K042928

[5] INDICATIONS for USE STATEMENT

510(k) Number (if known): K042928

Device Name: GLOBAL SPINAL FIXATION SYSTEM™.

Indications for Use: The GLOBAL SPINAL FIXATION SYSTEM™ posterior spinal fixation device is a pedicle screw system 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.

In addition, the GLOBAL SPINAL FIXATION 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 the thoracic, lumbar and sacral spine: degenerative Spondylolisthesis with objective evidence of neurological impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor and failed previous fusion (pseudarthrosis).

Prescription Use X **OR Over-the-Counter Use**_____**(Per 21 CFR 801.109)**
(Optional Format 1-2-96)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Mark N Milhaus

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

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