JUN 2 7 2003

K031585
page 1 of 2

**510(k) SUMMARY**

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

Submission Information:

Contact: Patrick Moore
Manager, Quality Assurance

Sponsor: U&i Corporation, America
6132 South 380 West
Murray, UT 84107
Phone: 801.262.3100
Fax: 801.262.3151

Date Prepared: May 20, 2003

Device Identification:

Trade Name: *OPTIMA™*, Spinal 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

Spinal Intervertebral Body Fixation Orthosis (KWQ) per 21 CFR § 888.3060

Substantially Equivalent Predicate Legally Marketed Devices:

The subject *OPTIMA™*, Spinal System is substantially equivalent in function, design, composition, labeling, and intended use to:

*OPTIMA™*, Spinal System MNH, MNI, KWQ – (K020279).
Micron Precision Engineering, AMT Spinal System – KWP, MNH -- (K002059)
Stryker® Spine, Xia™ Spinal System -- MNH, MNI, KWQ -- (K001319)

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

K031585
page 2 of 2

Device Description:

The *OPTIMA*™ Spinal System is a top-loading multiple component, anterior / posterior spinal fixation system which consists of pedicle screws, rods, set screws, connectors, and a transverse (cross) linking mechanism.

The *OPTIMA*™ system will allow surgeons to build a spinal implant construct to stabilize and promote spinal fusion. The *OPTIMA*™ implant system components are supplied non-sterile are single use and are fabricated from titanium alloy (Ti-6Al-4V ELI) that conforms to ASTM F 136. Various sizes of these implants are available. Specialized instruments made from surgical grade stainless steel are available for the application and removal of the *OPTIMA*™ system

Indications for Use:

The *OPTIMA*™ 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 *OPTIMA*™ 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 (pseudoarthrosis).

When used as an anterior screw fixation system, the *OPTIMA*™ is indicated for patients with degenerative disc disease which is defined as back pain of the 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.

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

JUN 2 7 2003

Mr. Patrick Moore
Manager, Quality Assurance
U&i Corporation, America
6132 South 380 West
Murray, UT 84107

Re: K031585
Trade/Device Name: OPTIMA™ Spinal System
Regulatory Numbers: 888.3060, 888.3070
Regulatory Names: Spinal intervertebral body fixation orthosis, Pedicle screw spinal system
Regulatory Class: II
Product Code: MNH, MNI, KWQ
Dated: May 20, 2003
Received: June 03, 2003

Dear Mr. Moore:

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 (301) 594-4659. 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/dsma/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

SECTION II

INDICATIONS for USE STATEMENT

**510(k) Number (if known):** K031585

**Device Name:** *OPTIMA™* Spinal System.

**Indications for Use:** The *OPTIMA™* 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.

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

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**Concurrence of CDRH, Office of Device Evaluation (ODE)**

for Mark N Melkerson

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

510(k) Number K031585

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