K061002
510(k) SUMMARY

NOV 15 2006

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, Euijungbu
Kyonggi-Do, Korea 480-050
Phone: 82-31- 852-0102(ext. 302)
Fax: 82-31-852-0107
E-mail: willerry@lycos.co.kr

Date Prepared: Mar. 14, 2006

Device Identification

Trade Name: Maxima™ Anterior Cervical Plate System

Classification Name: Spinal Intervertebral Body Fixation Orthosis (KWQ)

Substantially Equivalent Predicate Legally Marketed Devices

The subject Maxima™ Anterior Cervical Plate System is substantially equivalent in intended use, materials, anatomical site to ZEPHIR™ Anterior Cervical Plate System (K994239, K030327)

Device Description

Maxima™ Anterior Cervical Plate System consists of a variety of shapes and sizes of Main Plates, screw, sub-plate, rivets and the associated instruments. The sub-plate is pre-assembled to the main plate and designed to prevent screws from backing out using the elastic behavior during the screw insertion. The rivets are also pre-assembled to the main plate and designed to assemble the sub-plate to the main plate firmly. Each component is subjected to a color anodizing process to differentiate the screw type and diameter and to make the surgical process easy. Screws can be inserted in the center hole of Main Plate – S type. Main Plate – S type are offered in no hole, one hole, two hole, three hole and ranges from 24mm to 108mm. Screws are available in lengths from 10mm to 20mm in 1mm increments. The screws have either a 3.5mm or 4.0mm diameter. Variable screw and Semi-fixed screw are provided. Variable screw provides more rotational and translational degree of freedom than Semi-Fixed screws.

The Maxima™ Anterior Cervical Plate 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.

Indications for Use:

The Maxima™ Anterior Cervical Plate System is intended for anterior fixation to the cervical spine. The specific clinical indications include:

degenerative disc disease (DDD) (defined as neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, trauma (i.e., fracture or dislocation), spinal stenosis, deformities or curvatures (i.e., scoliosis, kyphosis, and/or lordosis), tumor, pseudoarthrosis, and failed previous fusion.

Statement of Technological Comparison:

Mechanical testing was carried out according to ASTM F1717-01 to validate the Maxima™ Anterior Cervical Plate System. The testing demonstrated substantially equivalent to the ZEPHIR™ Anterior Cervical Plate System (K994239, K030327) in terms of intended use, materials, and anatomical sites.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

U&I Corporation
c/o Mr. D. K. Rah
529-1 YongHyun-Dong
Euijungbu, Kyonggi-Do, Korea 480-050

NOV 15 2006

Re: K061002
Trade Name: Maxima™ Anterior Cervical Plate System
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal Intervertebral Body Fixation Orthosis
Regulatory Class: II
Product Code: KWQ
Dated: October 23, 2006
Received: October 25, 2006

Dear Mr. Rah:

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.

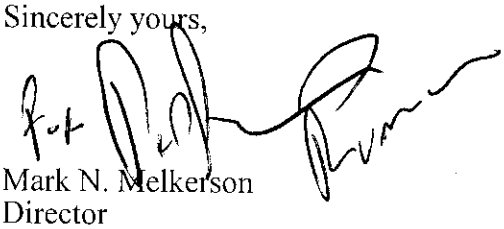
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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.

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,



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 STATEMENT

510(k) Number (if known): K061002

Device Name: Maxima™ Anterior Cervical Plate System.

Indications for Use: The Maxima™ Anterior Cervical Plate System is intended for anterior fixation to the cervical spine. The specific clinical indications include:

degenerative disc disease (DDD) (defined as neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, trauma (i.e., fracture or dislocation), spinal stenosis, deformities or curvatures (i.e., scoliosis, kyphosis, and/or lordosis), tumor, pseudoarthrosis, and failed previous fusion.

Prescription Use X **OR** **Over-the-Counter Use**
(Per 21 CFR 801 Subpart D) **(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 K061002