

JUL 22 2010

### 510(k) SUMMARY

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

#### Submission Information

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Date prepared: July 1, 2010

**Device Identification**

Trade Name: VENUS BASIC Spinal Fixation System  
Common Name: Pedicle Screw Spinal Fixation System  
Classification Name: Pedicle Screw Spinal System (21CFR 888.3070)  
Product Code: MNH, MNI

**Substantially Equivalent Predicate Legally Marketed Devices**

The subject device, VENUS BASIC Spinal Fixation System, is substantially equivalent to OPTIMA™, Spinal System manufactured by U & I Co., Ltd which was cleared for marketing as K031585, the Global Spinal Fixation System manufactured by D.K.M. Co., Ltd which was cleared for marketing as K001668, the 4CIS Vane Spine System manufactured by Solco Biomedical Co., Ltd which was cleared for marketing as K060702 and the EOS Spinal System manufactured by Korea Bone Bank Co., Ltd which was cleared for marketing as K082509.

**Device Description**

The VENUS BASIC Spinal Fixation System is a top-loading multiple component, posterior spinal fixation system which consists of pedicle screws, rods, nuts, and a transverse (cross) linking mechanism.

The VENUS BASIC Spinal Fixation System will allow surgeons to build a spinal implant construct to stabilize and promote spinal fusion. VENUS BASIC Spinal Fixation System implant components are supplied non-sterile are single use and are fabricated from titanium alloy (Ti-6Al-4V ELI) that conforms to ASTM F136. Various sizes of these implants are available. Specialized instruments are available for the application and removal of the VENUS BASIC Spinal Fixation System

**Indications for Use**

The VENUS BASIC 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 VENUS BASIC 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).

#### **Performance Data**

Mechanical testing as listed in **APPENDIX 3** that was conducted in accordance with ASTM F1717 demonstrates equivalence to the above predicate devices.

Mechanical test reports were completed for the following test methods:

- Static test: Tension, Compression and Torsion test report (ASTM F1717-04)
- Dynamic test: Fatigue test report (ASTM F1717-04)

#### **Conclusion**

Testing and other comparisons have established that the VENUS BASIC Spinal Fixation System is substantially equivalent in design, materials, indications, and performance to other predicate devices.



Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Room -WO66-G609  
Silver Spring, MD 20993-0002

L&K Biomed Co., Ltd.  
% Ms. Hee Kyeong Joo  
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Seoul, 153-803, Republic of Korea

JUL 22 2010

Re: K100706

Trade/Device Name: VENUS BASIC Spinal Fixation System  
Regulation Number: 21 CFR 888.3070  
Regulation Name: Pedicle screw spinal system  
Regulatory Class: Class II  
Product Code: MNH, MNI  
Dated: July 13, 2010  
Received: July 16, 2010

Dear Ms. Joo:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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.

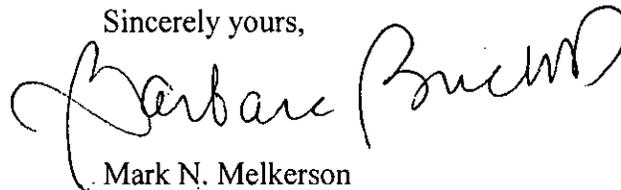
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,



Mark N. Melkerson  
Director  
Division of Surgical, Orthopedic  
And Restorative Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

**Indications for Use**

510(k) Number (if known): K100706

Device Name: VENUS BASIC Spinal Fixation System

Indications for Use:

The VENUS BASIC Spinal Fixation System are 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 VENUS BASIC Spinal Fixation System are 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    
 (Part 21 CFR 801 Subpart D)

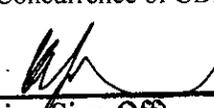
AND/OR

Over-The-Counter Use \_\_\_\_\_   
 (21 CFR 801 Subpart C)

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

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Concurrence of CDRH, Office of Device Evaluation (ODE)

  
\_\_\_\_\_  
(Division Sign-Off)  
Division of Surgical, Orthopedic,  
and Restorative Devices

510(k) Number K100706