510(k) SUMMARY

FEB - 9 2011

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

1. **Submission Information**

Submitter: L&K BIOMED Co., Ltd.

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E-mail: hkjoo83@gmail.com

Date prepared: October 15, 2010

2. **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

3. **Substantially Equivalent Predicate Legally Marketed Devices**

The subject VENUS BASIC Spinal Fixation System is substantially equivalent in function, design, composition, labeling and intended use to:

- L&K BIOMED Co., Ltd. VENUS BASIC Spinal Fixation System(K100706)
- D.K.M. Co., Ltd. Global Spinal Fixation System (K001668)
- U & I Co., Ltd. OPTIMA™ Spinal System (K091725, K051971, K042928, K031585, K024096)
- Solco Biomedical Co., Ltd. 4CIS Vane Spine System (K081145,K082453,K060702,K050471,K043578)
- Korea Bone Bank Co., Ltd. EOS Spinal System (K082509)

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

4. Device Description

The VENUS BASIC Spinal Fixation System is a top-loading multiple component, posterior spinal fixation system which consists of pedicle screws, rods, set screws, 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 implants components are supplied non-sterile are single use and are fabricated from titanium alloy (Ti-6Al-4V ELI) that conforms to ASTM F136.

The purpose of this submission is to add components of the cannulated polyaxial pedicle screws in VENUS BASIC Spinal Fixation System. Various sizes of these implants are available.

5. 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).

6. Performance Data

Mechanical testing as listed in **Attachment 8** that was conducted in accordance with static compression/tension/torsion and fatigue test per ASTM F 1717 demonstrates equivalence to the above predicate devices.

7. 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.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

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% Ms. Hee Kyeong Joo
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Geumcheon-gu, Seoul 153-803
Republic of Korea

FEB - 9 2011

Re: K103085
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: January 05, 2011
Received: January 10, 2011

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" (21CFR 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 : K103085

Device Name : VENUS BASIC Spinal Fixation System

Indications for Use :

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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 OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number K103085