

MAR - 7 2011

**510(k) Summary**

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

Date: 09/02/2010

**1. Submission information:**

Submitter: Min Seob Kim  
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Seoul, South Korea  
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**2. Device Information**

Trade Name:	Pallas M Spinal System
Common Name:	Pedicle Screw Spinal Fixation System
Classification Name:	Spinal Pedicle Fixation Spondylolisthesis Spinal Fixation
Product Code:	MNH, MNI
Regulation Number:	21 CFR 888.3070

**3. General Description**

The Pallas M Spinal System consists of rods, screws, revision rod system, lilac rod system, Miss pedicle screw system and associated instruments. The Pallas M Spinal System will allow surgeons to build a spinal implant construct to stabilize and promote spinal fusion. The Pallas M Spinal System components are supplied non-sterile, single use and fabricated from titanium alloy (Ti-6Al-4V ELI) that conforms to ASTM F136. Various sizes of these implants and specialized instruments are available for the application and removal of the Pallas M Spinal System. The products are supplied clean and "NON STERILE".

**4. Indication for Use**

The Pallas M Spinal system is intended for posterior, noncervical pedicle and non-pedicle fixation 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).

**5. Materials:**

The devices are manufactured from Ti6Al-4V ELI alloy per ASTM and ISO Standards.

**6. Performance Data:**

Performance data per ASTM F1717 were submitted to characterize the subject Pallas M Spinal System components addressed in this notification. Bench testing (static and dynamic axial compression bending test and static torsion test of the worst case Pallas M Spinal System structure) has been performed as listed in section 10. *Mechanical testing* (appendix 1-mechanical testing report) in accordance with ASTM F 1717-04-Standard Test Method for Spinal Implant Constructs in a Vertebrectomy Model.

**7. Predicate Devices:**

The subject device is substantially equivalent to the following predicate devices:

- \* EOS Spinal System (Korea Bone Bank Co., Ltd.; K082509)
- \* GSS Pedicle Screw System (GS Medical Co., Ltd.; K053573)

**8. Comparison to Predicate Devices:**

Testing and other comparisons have established that the subject of Pallas M Spinal System is substantially equivalent in design, materials, indications and intended use, packaging, labeling, and performance to other predicate devices of the type currently marketed in the U.S.

**9. Conclusion**

Based on the information provided in this premarket notification, Korea Bone Bank Co., Ltd . concludes that The Palla M Spinal System is safe, effective and substantially equivalent to the predicate devices as described herein.



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

Korea Bone Bank Co., Ltd.  
% Kodent Inc.  
Ms. Joyce Bang  
325 N. Puente Street, Unit B  
Brea, California 92821

MAR - 7 2011

Re: K102574

Trade/Device Name: Pallas M Spinal System  
Regulation Number: 21 CFR 888.3070  
Regulation Name: Pedicle screw spinal system  
Regulatory Class: Class II  
Product Code: MNH, MNI  
Dated: February 14, 2011  
Received: February 14, 2011

Dear Ms. Bang:

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.

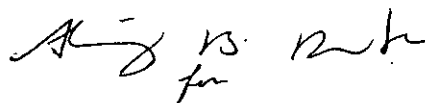
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

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/ucml15809.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,

A handwritten signature in black ink, appearing to read "Mark N. Melkerson" with a stylized flourish at the end.

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

Enclosure

**Indication for Use**

510(K) Number (if known):     K102574    

Device Name: Pallas M Spinal System

**Indication for Use:**

The Pallas M Spinal system is intended for posterior, noncervical pedicle and non-pedicle fixation 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    

AND/OR

Over-The-Counter                     

(Part 21 CFR 801 Subpart D)

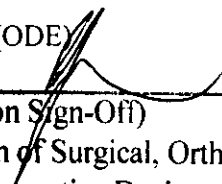
(Per 21 CFR 801 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Page 1 of 1

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