MAR 2 3 2012

12. 510(k) Summary

Submission information:

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345-30, Gasandong, Keumcheongu,
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Official Correspondent:
Kodent Inc.
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Date prepared: 3/22/2012

Device Information:

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

General Description:
The Pallas M Spinal System consists of rods, screws, revision rod system, lilac rod system, MIS 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".

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).

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

Performance Data:
No additional testing for this 510(k) submission was performed.

Predicate Devices:
The subject device is substantially equivalent to the following predicate devices:
* Pallas M Spinal System (Korea Bone Bank Co., Ltd.; K102574)

Comparison to Predicate Devices:
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 device of the type currently marketed in the U.S.
The difference between the subject device and the predicate device is the addition of curved rods and new surgical instruments.

Conclusion:
Based on the information provided in this premarket notification, Korea Bone Bank Co., Ltd . concludes that The Pallas 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.
% Ms. April Lee
Kodent, Inc.
325 N. Puente St., Unit B
Brea, California 92821

MAR 23 2012

Re: K120538
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 22, 2012
Received: February 22, 2012

Dear Ms. Lee:

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

Indication for Use

510(K) Number (if known): K120538

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)

(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 Surgical, Orthopedic,
and Restorative Devices

510(k) Number K120538