510(k) Summary

JUL 19 2010

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Device Information

Trade Name: Fixpine II 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

General Description
The Fixpine II System is a top-loading multiple component, posterior spinal fixation system which consists fixation system which consists of pedicle screws, rods, set screws, connectors, and a transverse (cross) linking mechanism.
The Fixpine II System will allow surgeons to build a spinal implant construct to stabilize and promote spinal fusion. The DIO Spinal System implant 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 are available.

Indication for Use
The Fixpine II System is a posterior 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 Fixpine II 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).

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

Performance Data:
Performance data per ASTM F1717 were submitted to characterize the subject Fixpine II

System components addressed in this notification. Bench testing (static and dynamic axial compression bending test and static torsion test of the worst case FixpineII system structure) as listed in section 2 (appendix III-brochure and IV-mechanical testing report) was performed in accordance with ASTM F 1717-04-Standard Test Method for Spinal Implant Constructs in a Vertebrectomy Model.

Predicate Devices:
The subject device is substantially equivalent to the following predicate devices:
* 4CIS® Vane Spine System (Solco Biomedical Co., Ltd.; K060702)
* GSS Pedicle Screw System (GS Medical Co., Ltd.; K053573)

Comparison to Predicate Devices:
Testing and other comparisons have established that the subject of Fixpine II 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.

Conclusion:
Based on the provided information in this premarket notification, it can be concluded that the subject device is substantial equivalent to the predicate devices and is safe and effective when used as intended.

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

JUL 19 2010

DIO Medical Co., Ltd.
% Kodent Inc.
Ms. Joyce Bang
13340 E. Firestone Boulevard, Suite J
Santa Fe Springs, California 90670

Re: K100765
Trade/Device Name: Fixpine II System
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle screw spinal system
Regulatory Class: Class II
Product Code: MNI, MNH, KWP
Dated: July 12, 2010
Received: July 15, 2010

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/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): _____K100765_____

Device Name: Fixpine II System

Indication for Use:
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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)
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(Division Sign-Off)
Division of Surgical Orthopedic,
and Restorative Devices

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