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510(k) Summary

As specified under 21 CFR 807.92,

Submitter:
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Device Information

Trade Name:	RexiousHook System
Classification Name:	Spinal Interlaminal Fixation Orthosis
Product Code:	KWP
Regulation Number:	888.3050
Date Prepared: 3/21/2012	

General Description

The Rexious Hook System is a top-loading posterior spinal fixation system which consists of hooks, rods, set screws, connectors and a transverse link system. The Rexious Hook System implant components are fabricated from titanium alloy (Ti6Al4V ELI) that conforms to ASTM F 136. Various sizes of these implants are available.

The Rexious Hook System can be used in the posterior plane providing unilateral and bilateral modes of fixation.

The Rexious Hook System design allows adjustment in both the sagittal and coronal planes permitting hook placement according to the best possible anatomic location and orientation.

Indication for Use

The Rexious Hook System is intended for use as a posterior, noncervical, nonpedicle system indicated for degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies); spondylolisthesis; trauma (i.e., fracture or dislocation); spinal stenosis; curvatures (i.e., scoliosis, kyphosis, and/or lordosis); tumor; pseudoarthrosis; and failed previous fusion. The Rexious Hook System can be used in conjunction with the Rexious Spinal Fixation System.

Materials:

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

Performance Data:

Performance tests per ASTM F1717 such as static compression bending, static tension, static torsion, and dynamic compression tests were submitted to characterize the subject Rexious Hook System components addressed in this notification.

Predicate Devices:

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

*U&I America, Spinal Hook System™ (K031595)

Comparison to Predicate Devices:

The Substantial equivalence of this device is based on equivalence in intended use, material, designs, and operational principles to the predicate device, U&I America, Spinal Hook System™ (K031595).

Conclusion

Both the performance testing and comparison to predicate device demonstrate that the subject device is as safe, as effective, and performs as well as the predicate device.

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

DIO Medical Co., Ltd.
% Kodent Incorporated
Ms. April Lee
325 North Puente Street, Unit B
Brea, California 92821

MAR 28 2012

Re: K113324
Trade/Device Name: Rexious Hook System
Regulation Number: 21 CFR 888.3050
Regulation Name: Spinal interlaminal fixation orthosis
Regulatory Class: II
Product Code: KWP
Dated: March 22, 2012
Received: March 26, 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): K113324

Device Name: Rexious Hook System

Indication for Use:

The Rexious Hook System is intended for use as a posterior, noncervical, nonpedicle system indicated for degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies); spondylolisthesis; trauma (i.e., fracture or dislocation); spinal stenosis; curvatures (i.e., scoliosis, kyphosis, and/or lordosis); tumor; pseudoarthrosis; and failed previous fusion. The Rexious Hook System can be used in conjunction with the Rexious Spinal Fixation System.

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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