

510(k) SUMMARY

JUN 25 2010

510 (K) Premarket Notification: **Medyssey Co. Ltd, Zenius™ Spinal System****1. Submitter/Sponsor:**

Medyssey Co. Ltd.

Patrick D. Moore, Official US Correspondent

722-3, 4F. Science Tower, Jihaeng-dong, Dongducheon-city, Gyeonggi-do,
Korea**Contact person:**

Patrick D. Moore

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Medyssey Co. Ltd.

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Date Prepared:

June 25th, 2010

2. Device Name:

Classification Name: Pedicle Screw Spinal Fixation System

Common/Generic Name: Pedicle Screw Spinal System

Trade Name: Medyssey Co. Ltd, *Zenius™* Spinal System**3. Device Classification(s):**Class II (88.3390) following Orthopedic and Rehabilitation Device Advisory
Review, for the requested indications:

- Spinal Pedicle Screw (MNI) 21 CFR § 888.3070
- Spondylolisthesis Spinal Fixation Device System (MNH) 21 CFR §
888.3070

4. Predicate Device:U&I Corporation, *OPTIMA™* Spinal System – MNI, MNH, KWQ -- (K020279 and
K024098)Medyssey Co. Ltd., *NOVEL™* Spinal System – MNH, MNI – (K081153)**5. Device Description:**

The Medyssey Co. Ltd., *Zenius™* Spinal System is a top-loading posterior spinal fixation system which consists of pedicle screws, rods, set screws, and a transverse (cross) linking mechanism. The Medyssey Co. Ltd., *Zenius™* Spinal System implant components are fabricated from titanium alloy (Ti-6Al-4V ELI) that conforms to ASTM F 136. Various sizes of these implants are available.

Specialized instruments made from surgical instrument grade stainless steel are available for the application and removal of the Medyssey Co. Ltd., *Zenius™* Spinal System implants.

6. Indications for Use:

The Medyssey Co. Ltd., *Zenius*TM Spinal System, a posterior spinal fixation device, indicated for skeletally mature patients receiving fusion by autogenous bone graft with removal of the implants after the attainment of a solid fusion and is intended to provide immobilization and stabilization of spinal segments as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar, and sacral spine: severe spondylolisthesis (grades 3 and 4) of the L5-S1 vertebra; degenerative spondylolisthesis with objective evidence of neurologic impairment; fracture; dislocation; scoliosis; kyphosis; spinal tumor; and failed previous fusion (pseudarthrosis).

7. Comparison with predicate device: The Medyssey Co. Ltd., *Zenius*TM Spinal System is substantially equivalent to the currently marketed U&I Corporation., *OPTIMA*TM Spinal System and Medyssey's Co. Ltd., *Novel*TM Spinal System. When considered for posterior applications, the Medyssey Co. Ltd., *Zenius*TM Spinal System, the Medyssey's Co. Ltd., *Novel*TM Spinal System and the U&I Corporation., *OPTIMA*TM Spinal System worst case constructs consist of a universal housing containing a pre-assembled pedicle screw and set screw. All three systems use vertical rods which are both placed into the housing. The set screws are subsequently tightened onto the rod, providing a completed implant assembly.

The principles of operation for the subject Medyssey Co. Ltd., *Zenius*TM Spinal System device, and the cited predicate technologies are similar. That is, each of these products employs similar indications for use, contraindications for use, warnings and precautions within labeling. The principles of operation of the subject device are directly equivalent to those of the cited predicates cleared by the Agency and currently being marketed.

Both the subject device and the predicate device were evaluated/tested per established requirements. The mechanical testing for both the predicate and the subject included static and fatigue testing performed per ASTM F 1717-04. Testing included: Static Compression Bending; Static Tension Bending; and Static Torsional Testing.

The subject device performed substantially equal or better in the above mentioned testing to that of the predicated devices.

Clinical tests: No clinical tests conducted on either the subject system nor the predicate systems.

Conclusion: The subject device was evaluated against the predicate devices for all performance, safety & effectiveness requirements and found as substantially equivalent to the predicate devices.



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

Medyssey Co., Ltd.
% Mr. Patrick.D. Moore
6170 South 380 West, Suite 200
Murray, Utah 84107

JUN 25 2010

Re: K093104

Trade/Device Name: Medyssey Co., Ltd. Zenius™ Spinal System
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle screw spinal system
Regulatory Class: Class II
Product Code: MNI, MNH
Dated: June 21, 2010
Received: June 21, 2010

Dear Mr. Moore:

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.

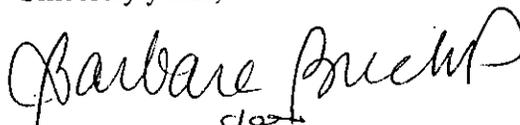
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

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" (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,



Mark N. Melkers

Director

Division of Surgical, Orthopedic

And Restorative Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

510(k) Number (if known): K093104

Device Name: Medyssey Co. Ltd., Zenius™ Spinal System

Indications for Use: The Medyssey Co. Ltd., Zenius™ Spinal System, a posterior spinal fixation device, indicated for skeletally mature patients receiving fusion by autogenous bone graft with removal of the implants after the attainment of a solid fusion and is intended to provide immobilization and stabilization of spinal segments as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar, and sacral spine: severe spondylolisthesis (grades 3 and 4) of the L5-S1 vertebra; degenerative spondylolisthesis with objective evidence of neurologic impairment; fracture; dislocation; scoliosis; kyphosis; spinal tumor; and failed previous fusion (pseudarthrosis).

Prescription Use OR Over-the-Counter Use _____ (Per 21 CFR801.109)
(Optional Format 1-2-96)

(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

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