K103147

DEC 16 2010

510(k) SUMMARY

"Special 510 (K): Device Modification" Premarket Notification: ***Novel III™* Spinal Fixation and Adjustable Bridge 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
Official US Correspondent
Medyssey Co. Ltd.
6170 South 380 West, Suite 200. Murray, Utah. 84107
Tel. 801-266-4811, Fax. 801-266-4363; E-Mail: pdmoore@jemospine.com

Date Prepared:

October 20, 2010

2. Device Name:

Classification Name:	Pedicle Screw Spinal Fixation System
Common/Generic Name:	Pedicle Screw Spinal System
Trade Name:	*Novel III* ™ Spinal Fixation and Adjustable Bridge 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
- Spinal Intervertebral Body Fixation Orthosis (KWQ) 21 CFR § 888.3060

4. Predicate Device:

Medyssey Co., Ltd., *Novel*™ Spinal System – MNI, MNH, KWQ -- (K081153)

5. Device Description:

The Novel *III*™ Spinal Fixation and Adjustable Bridge System is a top-loading posterior spinal fixation system which consists of pedicle screws, rods, set screws, and a transverse (cross) linking mechanism. The *Novel III* ™ Spinal Fixation and Adjustable Bridge 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.

p. 1 of 2

K10 3147

Specialized instruments made from surgical instrument grade stainless steel are available for the application and removal of the *Novel III*™ Spinal Fixation and Adjustable Bridge System implants.

6. Intended Use:
The Novel III Spinal System is a pedicle screw system indicated for the treatment of severe Spondylolisthesis (Grade 3 and 4) of the L5-S 1 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 Novel Spinal 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).

7. Comparison with predicate device: The *Novel III*™ Spinal System is substantially equivalent to the currently marketed *Novel*™ Spinal System. When considered for anterior applications, both the *Novel III*™ Spinal Fixation and Adjustable Bridge System and the *Novel*™ Spinal System worst case constructs consist of the same universal housing containing the same pre-assembled pedicle screw and set screw. Both systems use the same vertical rods which are both placed into the housing. The same set screws are subsequently tightened onto the rod, providing a completed implant assembly.

The principles of operation for the subject *Novel III*™ Spinal Fixation and Adjustable Bridge System device, and the cited predicate technologies are same. That is, each of these products employs the same 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.

The design and development process of the manufacturer of subject system and Predicate system conforms to 21 CFR part 820, ISO 9001 and ISO 13485 quality systems.

The subject and predicate device was evaluated/tested per established requirements.

The predicate device underwent mechanical testing included Static Compression Bending; Static Tension Bending; Static Torsional; also Dynamic Compression Fatigue Testing. All testing performed per ASTM F 1717-04. The subject device contains dimensionally modified components (not worst case) and therefore not subject to ASTM F 1717-04 additional testing.

p. 2 of 2

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

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

DEC 16 2010

Re: K103147
Trade/Device Name: Novel III™ Spinal Fixation and Adjustable Bridge System
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle screw spinal system
Regulatory Class: Class II
Product Code: MNI, MNH, KWQ
Dated: November 30, 2010
Received: December 2, 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.

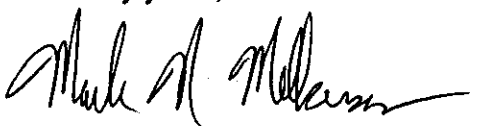
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's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

K103147

510(k) Number (original): ~~K081153~~
"~~Special 510(k): Device Modification~~" Number (if known):

DEC 16 2010

Device Name: *Novel III*^{TM} Spinal Fixation and Adjustable Bridge System

Indications for Use: The Novel III Spinal System is a pedicle screw system indicated for the treatment of severe Spondylolisthesis (Grade 3 and 4) of the L5-S 1 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 Novel Spinal 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).

Prescription Use____X____ OR Over-the-Counter Use_____(Per 21 CFR 801.109)
(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

510(k) Number K103147

p. 1.21