510(k) Summary

JAN 2 5 2013

Company:

Medyssey Co. Ltd.
722-3, 4F, Science Tower 4F
Dongducheon City
Gyeonggido, Korea
Tel: 82-31-879-0414
FAX: 82-31-879-0415

Contact:

Michael Kvitnitsky
Chief Operating Officer
Medyssey Co. Ltd
8001 N. Lincoln Ave.
Suite 401
Skokie, IL 60077
Tel: 847-982-0100
FAX: 888-518-9070

Date Prepared: August 9, 2010

Proprietary Name: Iliad Pedicle Screws (formerly Novel)
Kora Pedicle Screws (formerly Novel Standard Buttress Thread Screw)
Zenius Pedicle Screws
Cobalt Chrome Rods

Device Class: Class III

Product Codes: MNI, MNH, NKB

Classification Name: Noncervical, Pedicle Screw System

Regulation Number: 21 CFR 888.3070

Predicate Device: Medyssey Co. Ltd, *Zenius* ™ Spinal System K103272 and K110283; the Medyssey Novel Spinal System K081153, K103147, and K110284; the Synthes Matrix Spine System K092929, K100634 and K100952; the Globus Revere Stabilization System K061202, K081195 K091782, K093294 and K100788; and the Aesculap S^4 MIS Cannulated Pedicle Screw System (K100623, K090657, K071945, K062085 and K032219)

Product Description: The Medyssey Co. Ltd., Cannulated Pedicle Screws are intended to be used with their respective (e.g. Zenius) top-loading posterior spinal fixation system which consists of pedicle screws, rods, set screws, and a transverse (cross) linking mechanism. The Medyssey Co. Ltd., Cannulated Pedicle Screw implant components are fabricated from titanium alloy (Ti-6Al-4V ELI) that conforms to ASTM F 136. Various sizes of these implants are available.

The Medyssey Co. Ltd., Cannulated Pedicle Screws can be used in the posterior plane providing unilateral and bilateral modes of fixation.

The Medyssey Co. Ltd., Cannulated Pedicle Screw Spinal design allows adjustment in both the sagittal and coronal planes permitting screw placement according to the best possible anatomic (spinal) location and orientation. This is accomplished by means of a mobile and non-mobile housing component which

houses the screw and the rod which accepts a setscrew which tightens against the rod which tightens head of the pedicle screw upon secure tightening interface of the set screw assembly with the rod.

The Cobalt Chrome Rods are for use with the Zenius or Iliad System.

Specialized instruments made from surgical instrument grade stainless steel are available for the application and removal of the Medyssey Co. Ltd., Cannulated Pedicle Screw implants.

Indications for Use:
The Medyssey Co. Ltd. Zenius, Iliad and Kora Spinal Systems are intended for posterior, noncervical pedicle fixation as an adjunct to fusion in skeletally mature patients using autograft and/or allograft for the following indications: degenerative disc disease (DDD) (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.

Summary of Technological Characteristics Illiad System:
The Medyssey Illiad (formerly Novel) Cannulated Pedicle Screws consists of a series of titaninum pedicle screws and rods. These screws are used with locking screws and instruments from the Illiad (formerly Novel System). Both the predicate and proposed pedicle screws are made from titanium. The proposed screw designs are the same as the current screw designs the only difference is the cannulation of the screws. The proposed rods are manufactured from Co-Cr-Mo; whereas, the predicate rods are manufactured from titanium alloy. There are no other differences between the proposed and predicate rods.

Medyssey has determined that the minor differences between proposed screws and rods to the predicate devices will not impact the safety or effectiveness of the pedicle screw systems for their intended use. Analysis has shown that the proposed screws and rods are equivalent to the predicate devices.

Summary of Technological Characteristics Zenius System:
The Medyssey Zenuis Cannulated Pedicle Screws consists of a series of titanium pedicle screws and rods. These screws are used with locking screws and instruments from the Zenius System. Both the predicate and proposed pedicle screws are made from titanium. The proposed screw designs are the same as the current screw designs the only difference is the cannulation of the screws. The proposed rods are manufactured from Co-Cr-Mo; whereas, the predicate rods are manufactured from titanium alloy. There are no other differences between the proposed and predicate rods.

Medyssey has determined that the minor differences between proposed screws and rods to the predicate devices will not impact the safety or effectiveness of the pedicle screw systems for their intended use. Analysis has shown that the proposed screws and rods are equivalent to the predicate devices.

Summary of Technological Characteristics Kora System:
The Medyssey Kora (formerly Novel Standard Buttress Screw) Cannulated Pedicle Screws consists of a series of titaninum pedicle screws and rods. These screws are used with locking screws and instruments from the Kora System (formerly Novel Standard Buttress Screw. Both the predicate and proposed pedicle screws are made from titanium. The proposed screw designs are the same as the current screw designs the only difference is the cannulation of the screws. The proposed rods are manufactured from Co-Cr-Mo; whereas, the predicate rods are manufactured from titanium alloy. There are no other differences between the proposed and predicate rods.

Medyssey has determined that the minor differences between proposed screws to the predicate devices will not impact the safety or effectiveness of the pedicle screw systems for their intended use. Analysis has shown that the proposed screws are equivalent to the predicate devices.

Identification of Legally Marketed Predicate Device:

Documentation was provided, which demonstrates that the subject Medyssey Cannulated Pedicle Screws and Co-Cr-Mo rods are substantially equivalent to the predicate devices the Novel and Zenius Spinal System. The proposed Medyssey device has the same indications for use and is manufactured from the same material. The minor differences in the design were evaluated through testing and do not affect the safety and efficacy of the screws for their intended use.

Brief Discussion of Non-Clinical Tests Submitted:

Numerous tests were performed on the Medyssey Cannulated Pedicle Screws and Co-Cr-Mo rods. The tests performed are recommended by the FDA guidance document on spinal system 510(k) submissions and include ASTM F1717-04. List of Tests is below:

- Static Compression
- Static Torsion
- Static Tension
- Dynamic Compression

Conclusions from Non-Clinical Tests:

Based on the testing and comparison analysis to the predicate devices provided in this premarket notification submission, Medyssey believes that the subject Cannulated Pedicle Screws and Co-Cr-Mo rods are substantially equivalent to the Novel and Zenius Screws.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

Medyssey Company Limited
% Mr. Michael Kvitnitsky
Chief Operating Officer
8001 North Lincoln Avenue, Suite 401
Skokie, Illinois 60077

Letter dated: January 25, 2013

Re: K121670
Trade/Device Name: Zenius, Iliad and Kora Spinal Systems
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle screw spinal system
Regulatory Class: Class III
Product Code: NKB, MNI, MNH
Dated: January 16, 2013
Received: January 22, 2013

Dear Mr. Kvitnitsky:

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

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Form

510(k) Number (if known): K121670

Device Name: Medyssey Zenius, Iliad and Kora Systems

Indications for Use:

The Medyssey Co. Ltd. Zenius, Iliad and Kora Spinal Systems are intended for posterior, noncervical pedicle fixation as an adjunct to fusion in skeletally mature patients using autograft and/or allograft for the following indications: degenerative disc disease (DDD) (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.

Prescription Use X (Per 21 CFR 801.109) OR Over-The-Counter Use ____ (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)

Ronald P. Jean -S

(Division Sign-Off)
Division of Orthopedic Devices
510(k) Number: K121670