DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

August 21, 2017

Medyssey USA, Inc.
% Christine Scifert, MS
Executive Vice President
MRC-X, LLC
6075 Poplar Avenue, Suite 500
Memphis, Tennessee 38119

Re: K171526
Trade/Device Name: Zenius™, Iliad™ and Kora™ Spinal Fixation Systems
Regulation Number: 21 CFR 888.3070
Regulation Name: Thoracolumbosacral pedicle screw system
Regulatory Class: Class II
Product Code: NKB
Dated: August 15, 2017
Received: August 16, 2017

Dear Ms. Scifert:

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 contact the Division of Industry and Consumer Education (DICE) 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. 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 Industry and Consumer Education (DICE) 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,

Katherine D. Kavlock -S

for

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

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K171526

Device Name
Zenius™, lliad™ and Kora™ Spinal Fixation Systems

Indications for Use *(Describe)*
The Medyssey Co, Ltd. Zenius™, lliad™ and Kora™ Spinal Fixation 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.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary - Special
Zenius™, Iliad™ and Kora™ Spinal Systems

May 24, 2017

Company: Medyssey USA, Inc.
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Elk Grove Village, IL 60007
U.S.A.
Tel: 1-847-427-0200
FAX: 1-888-518-9070

Primary Contact: Kim Strohkirch
Phone: 901-361-2037

Company Contact: Shawn Kim, Director
Medyssey USA

Trade Name: Zenius™, lliad™ and Kora™ Spinal Fixation Systems

Common Name: Pedicle Screw System

Classification: Class II

Regulation Number: 21 CFR 888.3070 (Thoracolumbosacral Pedicle Screw Spinal System)

Panel: 87- Orthopedic

Product Code: NKB

Predicate Devices:

Primary Predicate Device:

- Medyssey: Iliad Pedicle Screws (formerly Novel) Kora Pedicle Screws (formerly Novel Standard Buttress Thread Screw) Zenius Pedicle Screws Cobalt Chrome Rods – K121670(Cleared 1/25/2013)

Additional Predicate Devices:

- Medyssey: Zenius Pedical Screws and Titanium Rods – K093104 (Cleared 6/25/2000) and K103272 (Cleared 12/29/2010)
- Medyssey: Novel Pedicle Screws and Titanium Rods – K081153 (Cleared 1/30/2009), K103147 (Cleared 12/16/2010), and K110284 (Cleared 6/8/2011)

Device Description:
The Zenius™ Spinal System, Internal Fixation Device for Spinal Surgery is comprised of: Rods, Pedicle Screw Assemblies, Compression Retaining Assemblies, and Transverse-Link Assemblies. Various forms and sizes of these implants are available so that adaptations can be utilized to account for the unique pathology of individual patients.

The Iliad™ Spinal Fixation and Adjustable Bridge System, Internal Fixation Device for Spinal Surgery is comprised of: Rods, Pedicle Screw Assemblies, Compression Retaining Assemblies, and Transverse-Link Assemblies. Various forms and sizes of these implants are available so that adaptations can be utilized to take into account the unique pathology of individual patients.

The Kora™ Spinal Fixation and Adjustable Bridge System, Internal Fixation Device for Spinal Surgery is comprised of: Rods, Pedicle Screw Assemblies, Compression Retaining Assemblies, and Transverse-Link Assemblies. Various forms and sizes of these implants are available so that adaptations can be utilized to take into account the unique pathology of individual patients.

Subject screws are manufactured from Ti6Al4V ELI per ASTM F136. The subject of this submission is the addition of smaller diameter cannulated screws to the spinal systems.

Indications for Use:
The Medyssey Co, Ltd. Zenius Spinal System is 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.

Substantial Equivalence:
The subject cannulated screws are substantially equivalent to the screws cleared in the following 510(k)s for the Zenius™, Iliad™ and Kora™ Systems with respect to indications for use, design, dimension, and materials.

Primary Predicate:
Medyssey: Iliad Pedicle Screws (formerly Novel) Kora Pedicle Screws (formerly Novel Standard Buttress Thread Screw) Zenius Pedicle Screws Cobalt Chrome Rods – K121670(Cleared 1/25/2013)

Secondary Predicate Devices:

- Medyssey: Zenius Pedical Screws and Titanium Rods – K093104 (Cleared 6/25/2000) and K103272 (Cleared 12/29/2010)
- Medyssey: Novel Pedicle Screws and Titanium Rods – K081153 (Cleared 1/30/2009), K103147 (Cleared 12/16/2010), and K110284 (Cleared 6/8/2011)

Performance Testing:
Mechanical testing was performed per ASTM F1717 (Static and Dynamic Compression Bending, Tensile Bending, Static Torsion) to establish that the mechanical properties of the subject devices are equivalent to the predicate devices. A summary of mechanical testing is provided in the Performance Testing - Bench section.