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

June 12, 2017

Medyssey USA, Inc.
% Kim Strohkirch, MS, MEM
Executive Vice President
MRC-X, LLC
6075 Poplar Ave
Memphis, TN 38119

Re: K171509
Trade/Device Name: Iliad® Pedicle Screw System and Zenius® Pedicle Screw System
Regulation Number: 21 CFR 888.3070
Regulation Name: Thoracolumbosacral Pedicle Screw System
Regulatory Class: Class II
Product Code: NKB
Dated: May 22, 2017
Received: May 23, 2017

Dear Ms. Strohkirch:

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 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 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,

Mark N. Melkerson -S

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)*

K171509

Device Name
Iliad® Pedicle Screw System and Zenius® Pedicle Screw System

Indications for Use *(Describe)*

The Medyssey Co, Ltd. lliad and Zenius 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.

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
Iliad® and Zenius® Spinal Systems

May 22, 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: Iliad® Pedicle Screw System and Zenius® Pedicle Screw System

Common Name: Pedicle Screw System

Classification: Class II

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

Panel: 87- Orthopedic

Product Code: NKB

Predicate Devices:

Primary Predicate Device:

- Medyssey: Iliad Pedicle Screw System and Zenius Pedicle Screw System-K142835 (Cleared 6/12/2015)

Device Description:

The lliad™ 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 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.

Subject rod connectors are manufactured from Ti6Al4V ELI per ASTM F136. The subject of this submission is the addition of hook type rod connectors to the Iliad™ and Zenius™ Systems.

Indications for Use:
The Medyssey Co, Ltd. lliad and Zenius 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.

Substantial Equivalence:
The subject cannulated screws are substantially equivalent to the screws cleared in the following 510(k)s for the Iliad™ and Zenius™ Systems with respect to indications for use, dimension, and materials. The subject connectors differ from the predicate connector in design. The subject connectors are open; predicate connectors are closed. Mechanical testing demonstrates that the subject device is substantially equivalent to the predicate device.

Primary Predicate Device:

- Medyssey: Iliad Pedicle Screw System and Zenius Pedicle Screw System-K142835 (Cleared 6/12/2015)

Performance Testing:
Axial grip testing was performed per ASTM F1798-13 to establish that the mechanical properties of the subject devices are equivalent to the predicate devices.