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

April 26, 2017

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

Re: K170964
Trade/Device Name: Zenius Spinal System
Regulation Number: 21 CFR 888.3070
Regulation Name: Thorocolumbosacral pedicle screw system
Regulatory Class: Class II
Product Code: NKB
Dated: March 28, 2017
Received: March 31, 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 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,

Vincent J. Devlin -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)*
K170964

Device Name
Zenius Spinal System

Indications for Use *(Describe)*
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.

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 Spinal System

April 26, 2017

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

Primary Contact: Christine Scifert, MS, MEM
Phone: 901-831-8053

Company Contact: Shawn Kim, Director
Medyssey USA

Trade Name: Zenius Spinal 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:

- Medyssey Iliad, Kora and Zenius Spinal Systems – K131878

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 take into account the unique pathology of individual patients.

All implantable components are manufactured from Ti6Al4V ELI per ASTM F136 and wrought Co-Cr-Mo alloy per ASTM F1537. The subject of this submission is the addition of variable rods to the Zenius™ System.

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 variable rod is substantially equivalent to the taper rod cleared in K131878 for the Zenius™ System with respect to indications for use, design, dimension, and materials:

Primary Predicate:

- Medyssey Iliad, Kora and Zenius Spinal Systems – K131878

While the subject variable rods are similar in indications, size, materials and geometry to the predicate, they are not identical. However, the modification to the connection component at the end of the variable rod does not present a new worst case and a rationale related to ASTM F1717 testing is provided.

Performance Testing:
A rationale related to ASTM F1717 testing is provided showing the subject variable rod to be substantially equivalent to the predicate rods cleared in K131878.