August 13, 2018

Medyssey USA, Inc.
% Ms. Margeaux Rogers
Senior Associate, Regulatory Affairs
Musculoskeletal Clinical Regulatory Advisers, LLC
1050 K Street NW, Suite 1000
Washington, District of Columbia 20001

Re: K181978
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: July 24, 2018
Received: July 24, 2018

Dear Ms. Rogers:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Ronald P. Jean -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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K181978

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

Indications for Use *(Describe)*
The Medyssey Co, Ltd. Zenius™, Iliad™ 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)*

[X] Prescription Use (Part 21 CFR 801 Subpart D) [ ] Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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5. 510(k) Summary

Manufacturer: Medyssey USA, Inc.
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Prepared By: Musculoskeletal Clinical Regulatory Advisers, LLC
1050 K Street NW, Suite 1000
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Phone: 202.552.5800

Date Prepared: July 24, 2018

Device Trade Name: Zenius™, Iliad™ and Kora™ Spinal Fixation Systems

Common Name: Pedicle Screw System

Classifications: 21 CFR §888.3070 – Thoracolumbosacral pedicle screw system

Class II

Product Codes: NKB

Primary Predicate Device: Zenius™, Iliad ™ and Kora™ Spinal Fixation Systems (K171526, K171509)

Indications for Use:
The Medyssey Co, Ltd. Zenius™, Iliad™ 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.

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.

The subject of this 510(k) is the addition of Z-Rods to the spinal systems.

Performance Testing:
Mechanical testing per ASTM F2193-14 was performed in accordance with the results of the risk analysis. Results demonstrated substantial equivalence compared to the predicate device.

Substantial Equivalence:
The subject Z-Rods are substantially equivalent to the rods cleared in K171526 and K171509 for the Zenius, Iliad and Kora Spinal Fixation Systems with respect to indications for use, dimensions and materials. The subject Z-Rods are pre-bent with 90° curvature. Mechanical testing per ASTM F2193-14 demonstrates that the subject device is substantially equivalent to the predicate devices.

Conclusion:
The subject 510(k) demonstrated the Zenius, Iliad and Kora Spinal Fixation Systems with the Z-Rod are substantially equivalent to the primary predicate device.