Medyssey USA, Inc.
% Kyle Kovach
Sr. Quality and Regulatory Engineer
JALEX Medical
27865 Clemens Road, Suite #3
Westlake, Ohio 44145

August 24, 2023

Re: K232218
Trade/Device Name: Zenius™ Spinal System
Regulation Number: 21 CFR 888.3070
Regulation Name: Thoracolumbosacral Pedicle Screw System
Regulatory Class: Class II
Product Code: NKB
Dated: July 26, 2023
Received: July 26, 2023

Dear Kyle Kovach:

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/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Eileen Cadel -S
Digitally signed by Eileen Cadel -S
Date: 2023.08.24 14:47:33 -04'00'

for

Colin O'Neill, M.B.E.
Assistant Director
DHT6B: Division of Spinal Devices
OHT6: Office of Orthopedic Devices
Office of Product Evaluation and Quality
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K232218

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.

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

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Special 510(k) Summary

Applicant:	Medyssey USA, Inc. 43176 Business Park Drive Suite 107 Temecula, CA 92590 USA
Establishment Registration Number:	3008692185
Date:	07/26/2023
Contact Person: **Contact Email:** **Contact Telephone: Contact** **Fax:**	Kyle Kovach, Senior Quality and Regulatory Engineer kkovach@jalexmedical.com (440) 787-5832 (440) 933-7839
Device Trade Name: Device **Common Name:** **Classification Name:** **Device Class:** **Reviewing Panel: Regulation** **Number: Classification** **Product Code:**	**Zenius™ Spinal System** Thoracolumbosacral Pedicle Screw System Thoracolumbosacral Pedicle Screw System II Orthopedic 888.3070 NKB
Primary Predicate Device:	Medyssey USA, Inc. Zenius™ System (K093104)
Additional Predicates:	Medyssey USA, Inc. Zenius™ System (K103272) Medyssey USA, Inc. Medyssey Cannulated Pedicle Screw (K121670) Medyssey USA, Inc. Zenius™, Iliad™, and Kora™ Spinal Fixation Systems (K171526)

Device Description:
The Zenius™ Spinal System, Internal Fixation Device for Spinal Surgery is comprised of: rods, pedicle screw assemblies, compression retaining assemblies, set screws 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 screws are manufactured from Ti6Al4V ELI per ASTM F136.

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.

Description of Modifications:
The Medyssey Zenius™ Spinal System is an updated version of a legally marketed previous generation of the device. The purpose of this submission is for Medyssey to obtain clearance for design changes that include updates to screw housing design, extension of screw length availability, addition of cannulation, and addition of fenestration to the screw body designs. There were no changes to material or sterilization parameters.

Summary of Technological Characteristics:
The Zenius™ Spinal System subject has the same intended use and fundamental scientific technology as the predicate devices. Table 1 below outlines a tabular comparison of the modified device and the predicate system to evaluate any differences in characteristics and features that may impact safety or effectiveness.

Table 1: Comparison of Subject and Predicate Device

	Subject Device	Primary Predicate Device	Additional Predicates	Comparison
Trade Name	• Zenius™ Spinal System -Zenius Pedicle Screws -Zenius II Pedicle Screws -Hedjet Screws -Hedjet Cannulated Poly-Axial Screws -Long Reduction Hole Poly-Axial Cap Screw -Hedjet Hole Poly-Axial Screws	• Zenius™ Spinal System -Zenius Pedicle Screws	• Zenius™ Spinal System -Zenius Pedicle Screws	Equivalent
Manufacturer	Medyssey Co. Ltd.	Medyssey Co. Ltd.	Medyssey Co. Ltd.	Equivalent
Classification Name	Thoracolumbosacral Pedicle Screw System	Thoracolumbosacral Pedicle Screw System	Thoracolumbosacral Pedicle Screw System	Equivalent
510(k) Number	n/a	K093104 K103272	K121670 K171526	N/A

Medyssey

	Subject Device	Primary Predicate Device	Additional Predicates	Comparison
Product Code	NKB	NKB	NKB	Equivalent
Regulation Number	888.3070	888.3070	888.3070	Equivalent
Regulation Medical Specialty	Orthopedic	Orthopedic	Orthopedic	Equivalent
Materials	Titanium Alloy (Ti6AL4V ELI per ASTM F136)	Titanium Alloy (Ti6AL4V ELI per ASTM F136)	Titanium Alloy (Ti6AL4V ELI per ASTM F136)	Equivalent
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.	The Medyssey Co, Ltd., Zenius Spinal System, a posterior spinal fixation device, indicated for skeletally mature patients receiving fusion by autogenous bone graft with removal of the implants after the attainment of a solid fusion and is intended to provide immobilization and stabilization of spinal segments as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar, and sacral spine: severe spondylolisthesis (grades 3 and 4) of the L5-S1 vertebra; degenerative spondylolisthesis with objective evidence of neurologic impairment; fracture; dislocation; scoliosis; kyphosis;	The Medyssey Co. Ltd., Zenius, Iliad and Kora Spinal Systems are intended for posterior, noncervical pedicle fixation 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; deformities or curvatures (i.e., scoliosis, kyphosis, and/or lordosis); tumor; pseudoarthrosis; and failed previous fusion.	Equivalent to the Additional Predicate

	Subject Device	Primary Predicate Device	Additional Predicates	Comparison
		spinal tumor; and failed previous fusion (pseudarthrosis).		
Device Description	The Zenius™ Spinal System, Internal Fixation Device for Spinal Surgery is comprised of: rods, pedicle screw assemblies, compression retaining assemblies, set screws 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 screws are manufactured from Ti6Al4V ELI per ASTM F136.	The Medyssey Co. Ltd., Zenius™ Spinal System is a top-loading posterior spinal fixation system which consists of pedicle screws, rods, set screws, and a transverse (cross) linking mechanism. The Medyssey Co. Ltd., Zenius™ Spinal System implant components are fabricated from titanium ally (Ti-6Al-4V ELI) that conforms to ASTM F136. Various sizes of these implants are available. Specialized instruments made from surgical instrument grade stainless steel are available for the application and removal of the Medyssey Co., Ltd., Zenius™ Spinal System implants.	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.	Equivalent to Additional Predicate

These aspects of the subject device were determined to be equivalent to the previous generation of the device as the two systems compare similarly in:

- Technological Characteristics and Intended Use/Indications for Use
- Device Function/Performance
- Materials and Manufacturing Processes
- Design Features
- Post-Processing Procedures, including Sterility and Shelf-Life Characteristics

Mechanical Testing:

Substantial equivalence is supported by the results of mechanical testing. Performance testing to support justification of safety and effectiveness compared to the predicate include evaluation of: static compression bending, static torsion, static tension, and dynamic compression bending as per ASTM F1717. Results support that modifications to the Zenius™ system screws did not introduce a worst-case scenario and the subject device performs as well or better than the predicate system screw.

Conclusion:

Based on the indications for use, technological characteristics, impact on mechanical performance, and overall comparison with the predicate device, the subject device has demonstrated substantial equivalence.