March 7, 2023

Medyssey USA, Inc.
% Jennifer Palinchik
President
Jalex Medical
27865 Clemens Rd., Suite #3
Westlake, Ohio 44145

Re: K230301
Trade/Device Name: Athena III Cervical Plate System
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal Intervertebral Body Fixation Orthosis
Regulatory Class: Class II
Product Code: KWQ
Dated: February 2, 2023
Received: February 3, 2023

Dear Jennifer Palinchik:

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,

Colin O'neill -S

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)*

K230301

Device Name
Athena III Cervical Plate System

Indications for Use *(Describe)*

The Athena III Cervical Plate System is intended for anterior interbody screw fixation of the cervical spine. The system is indicated for use in the temporary stabilization of the anterior spine during the development of a solid spinal fusion in patients with degenerative disc disease (as defined by neck pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies), trauma (including fractures), tumors, deformity (defined as kyphosis, lordosis, or scoliosis), pseudoarthrosis, and/or failed previous fusions. The Athena III Cervical Plate System can be implanted in the sub-axial cervical spine from C3 through C7 levels.

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:	February 2, 2023
Contact Person:	Jennifer Palinchik, President
Contact Email:	jpalinchik@jalexmedical.com
Contact Telephone:	(440) 935-3282
Contact Fax:	(440) 933-7839
Device Trade Name:	**Athena III Cervical Plate System**
Device Classification Name:	Spinal Intervertebral Body Fixation Orthosis
Device Class:	II
Reviewing Panel:	Orthopedic
Regulation Number:	888.3060
Classification Product Code:	KWQ
Predicate Device:	Medyssey USA, Inc. Athena II Cervical Plate System (K183409)

Device Description:
The Athena III Cervical Plate System is an anterior cervical plating system offered pre-lordosed with large graft visibility windows intended for anterior screw fixation to the cervical spine. The components of the Athena III Cervical Plate System are manufactured from titanium alloy (Ti-6Al-4V), as per ASTM F136. The system consists of a variety of shapes and sizes of bone plates and screws. Implant components are anodized per AMS 2487A.

Indications for Use:
The Athena III Cervical Plate System is intended for anterior interbody screw fixation of the cervical spine. The system is indicated for use in the temporary stabilization of the anterior spine during the development of a solid spinal fusion in patients with degenerative disc disease (as defined by neck pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies), trauma (including fractures), tumors, deformity (defined as kyphosis, lordosis, or scoliosis), pseudoarthrosis, and/or failed previous fusions. The Athena III Cervical Plate System can be implanted in the sub-axial cervical spine from C3 through C7 levels.

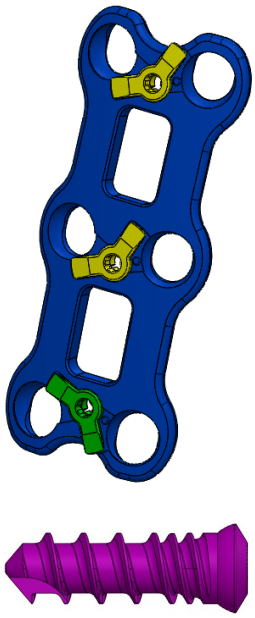
Special 510(k) Submission – Athena III Cervical Plate System

Section VII – 510(k) Summary

Description of Modifications:

The Medyssey Athena III Cervical Plate System is an updated 3rd generation version of a legally marketed previous generation of the device, the Athena II Cervical Plate System. The purpose of this submission is for Medyssey to obtain clearance for design changes that include modification of screw design and a modified wing plate design. Table 7.1 below displays a visual comparison of the modified subject device consisting of the cervical plate and screw alongside the predicate device (not to scale). There were no changes to material or sterilization parameters. These changes and relevant risks are discussed in greater detail within this submission.

Table 7.1: Device Comparison

Subject Device: **Athena III Cervical Plate System**	Predicate Device: **Athena II Cervical Plate System**
	

Special 510(k) Submission – Athena III Cervical Plate System

Section VII – 510(k) Summary

Summary of Technological Characteristics:

The Athena III Cervical Plate System and the predicate have the same intended use and fundamental scientific technology. Table 7.2 below outlines a tabular comparison of the modified device and the predicate Athena II Cervical Plate System to evaluate any differences in characteristics and features that may impact safety or effectiveness.

Table 7.2: Comparison of Subject and Predicate Device

	Modified Subject Device	Predicate Device	Comparison
Trade Name	Athena III Cervical Plate System	Athena II Cervical Plate System	Equivalent
Manufacturer	Medyssey	Medyssey	Equivalent
Classification Name	Spinal Intervertebral Body Fixation Orthosis	Spinal Intervertebral Body Fixation Orthosis	Equivalent
510(k) Number	n/a	K183409	Equivalent
Product Code	KWQ	KWQ	Equivalent
Regulation Number	888.3060	888.3060	Equivalent
Regulation Medical Specialty	Orthopedic	Orthopedic	Equivalent
Materials	Titanium Alloy (Ti6AL4VELI)	Titanium Alloy (Ti6AL4VELI)	Equivalent
Indications for Use	The Athena Cervical III Plate System is intended for anterior interbody screw fixation of the cervical spine. The system is indicated for use in the temporary stabilization of the anterior spine during the development of a solid spinal fusion in patients with degenerative disc disease (as defined by neck pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies), trauma (including fractures), tumors, deformity (defined as kyphosis, lordosis, or scoliosis), pseudoarthrosis, and/or failed previous fusions. The Athena III Cervical Plate System can be implanted in the sub-axial cervical spine from C3 through C7 levels.	The Athena II Cervical Plate System is intended for anterior interbody screw fixation of the cervical spine. The system is indicated for use in the temporary stabilization of the anterior spine during the development of a solid spinal fusion in patients with degenerative disc disease (as defined by neck pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies), trauma (including fractures), tumors, deformity (defined as kyphosis, lordosis, or scoliosis), pseudoarthrosis, and/or failed previous fusions. The Athena II Cervical Plate System can be implanted in the sub-axial cervical spine from C3 through C7 levels.	Equivalent

Medyssey

Special 510(k) Submission – Athena III Cervical Plate System

Section VII – 510(k) Summary

	Modified Subject Device	Predicate Device	Comparison
Device Description	The Athena III Cervical Plate System is an anterior cervical plating system offered pre-lordosed with large graft visibility windows intended for anterior screw fixation to the cervical spine. The components of the Athena III Cervical Plate System are manufactured from titanium alloy (Ti-6Al-4V) as described in ASTM F136. The Athena III Cervical Plate System consists of a variety of shapes and sizes of bone plates and screws. Implant components are anodized per AMS 2487A.	The Athena II Cervical Plate System is an anterior cervical plating system offered pre-lordosed with large graft visibility windows intended for anterior screw fixation to the cervical spine. The components of the Athena II Cervical Plate System are manufactured from titanium alloy (Ti-6Al-4V) as described in ASTM F136. The Athena II Cervical Plate System consists of a variety of shapes and sizes of bone plates and screws. Implant components are anodized per AMS 2487A.	Equivalent

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:

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

Mechanical Testing:

A full suite of mechanical testing was performed to evaluate performance of the modifications to the cervical plates and screws in an effort to verify strength and safety. Substantial equivalence is supported by the results of mechanical testing, including static compression bending, static torsion, static tension, and dynamic compression bending as per ASTM F1717. Results and discussion of the testing is further discussed within the submission.

Conclusion:

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