Medyssey USA, Inc.
% Rich Jansen
Consultant
Silver Pine Consulting, LLC.
3851 Mossy Oak Drive
Ft. Myers, Florida 33905

July 20, 2018

Re: K180022
Trade/Device Name: Athena Cervical Plate System
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal Intervertebral Body Fixation Orthosis
Regulatory Class: Class II
Product Code: KWQ
Dated: June 26, 2018
Received: June 27, 2018

Dear Mr. Jansen:

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.

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,

Melissa Hall -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)*
K180022

Device Name
Athena Cervical Plate System

Indications for Use *(Describe)*
The Athena 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 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.

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510(k) Summary

Date Prepared: June 26, 2018
Submitter: Shawn Kim
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888-518-9070 (fax)

Regulatory Contact: Rich Jansen, Pharm. D.
Silver Pine Consulting

Product

Trade Names:	Athena Cervical Plate System
Product Class:	Class II
Classification:	21 CFR §888.3060 Spinal Intervertebral Body Fixation Orthosis
Name:	Cervical Plate System
Product Codes:	KWQ
Panel Code:	87

Device Descriptions:
The Medyssey Athena Cervical Plate System is designed to provide mechanical support while biologic fusion takes place. The system consists of multiple plate sizes and screws to accommodate various patients' anatomy. The plates are available in fixed and variable forms to allow for fixed attachment or implantation at variable angles.

Indications for Use:
The Athena 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 Cervical Plate System can be implanted in the sub-axial cervical spine from C3 through C7 levels.

Predicate Device(s):
The primary predicate device is the Vertebron Cervical Plate (K081567). An additional predicate device is the Vectra Cervical Plate System (K050451).
The Athena Cervical Plate was compared to the predicated devices in regards to:

- Indications for Use
- Materials
- Number of levels covered
- Plate Dimensions
- Screw Dimensions
- Design features and technological characteristics

The Athena Plate is considered to be substantially equivalent to one or both of the predicate devices in all elements of comparison

Performance Standards:
The pre-clinical testing was performed by an independent laboratory. Testing was conducted per ASTM F1717-13.
Testing included:

Test	Result
Static Torsion Bending	Substantially equivalent to predicates
Static Compression Bending	Substantially equivalent to predicates
Dynamic Compression Bending to 5MM cycles	Substantially equivalent to predicates

Conclusion:
Medyssey concludes that the Athena Cervical Plate system is as safe, as effective, and performs as well as or better than the legally marketed predicate devices.