February 11, 2019

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

Re: K183409
Trade/Device Name: Athena II Cervical Plate System
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal intervertebral body fixation orthosis
Regulatory Class: Class II
Product Code: KWQ
Dated: December 6, 2018
Received: December 10, 2018

Dear Dr. 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. 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: January 31, 2017
See PRA Statement below

510(k) Number *(if known)*
K183409

Device Name:
Athena II Cervical Plate System

Indications for Use *(Describe)*

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.

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)

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

510(k) Summary

Date Prepared: December 3, 2018
Submitter: Shawn Kim
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847-427-0200
888-518-9070 (fax)

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

Product

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

Device Descriptions:
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.

Indications for Use:
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.

Predicate Device(s):
The primary predicate device is the Athena Cervical Plate System (K180022). Additional predicate devices include the Vertebron Cervical Plate (K081567) and the Vectra Cervical Plate System (K050451).

The Athena II Cervical Plate System 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 II Cervical Plate System is considered to be substantially equivalent to one or all 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 Compression Bending	Substantially equivalent to predicates
Static Torsion	Substantially equivalent to predicates
Static Tension	Substantially equivalent to predicates
Dynamic Compression Bending to 5MM cycles	Substantially equivalent to predicates

Conclusion:
Medyssey concludes that the Athena II Cervical Plate system is substantially equivalent to the predicate devices.