November 2, 2017

Medyssey Co., Ltd.
% Ms. Cheryl L. Wagoner
Principal Consultant/Owner
Wagoner Consulting LLC
P.O. Box 15729
Wilmington, North Carolina 28408

Re: K170341
Trade/Device Name: Medussa-PL Cage
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: MAX
Dated: October 2, 2017
Received: October 4, 2017

Dear Ms. Wagoner:

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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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,

Mark N. Melkerson -S

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)*
K170341

Device Name
Medussa-PL Cage

Indications for Use *(Describe)*
The Medussa-PL Cage is indicated for use in skeletally mature patients with Degenerative Disc Disease (DDD) at one or two contiguous levels from L2-S1. DDD is defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies. Patients should have received 6 months of non-operative treatment prior to treatment with the devices. The device must be used with supplemental fixation. These DDD patients may also have up to Grade 1 spondylolisthesis or retrolisthesis at the involved level(s). It is indicated to be used with autograft bone.

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
K170341
(as required by 21 CFR 807.92)

Date Prepared	10/31/2017
Manufacturer	Medyssey Co., Ltd.
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Telephone	847-427-0200
Fax	888-518-9070
email	shawn@medyssey.com

Trade Name	Medussa-PL Cage
Common Name	Intervertebral Body Fusion Device
Panel Code	Orthopaedics/87
Classification Name	Intervertebral Body Fusion Device
Class	Class II
Regulation Number	21 CFR 888.3080
Product Code	MAX

Name of Predicate Device	**510(k) #**	**Manufacturer**
Medyssey LP Cage (Primary)	K110067	Medyssey Co., Ltd
4-WEB ALIF SPINAL TRUSS SYSTEM (STS)	K112316	4-WEB, INC.

Description	The Medussa-PL Cage is comprised of a variety of implant sizes and instrumentation to accommodate various patient anatomy and pathology. All implantable components are manufactured with an additive manufacturing technology from medical grade titanium alloy Ti6Al4V-ELI per ASTM F136 and ASTM 3001. The cages are intended to be implanted via a Posterior Lumbar Intervertebral (PLIF) approach. Implants are single use and the system is provided sterile.

Indications and Intended Use	The Medussa-PL Cage is indicated for use in skeletally mature patients with Degenerative Disc Disease (DDD) at one or two contiguous levels from L2-S1. DDD is defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies. Patients should have received 6 months of non-operative treatment prior to treatment with the devices. The device must be used with supplemental fixation. These DDD patients may also have up to Grade 1 spondylolisthesis or retrolisthesis at the involved level(s). It is indicated to be used with autograft bone.

Technological Characteristics and Substantial Equivalence	Documentation was provided to demonstrate that the Subject device, Medussa-PL Cage is substantially equivalent to the Predicate Medyssey LP Cage (K110067). The Subject device is substantially equivalent to the predicate device in intended use, indications for use, materials, technological characteristics, and labeling.

Performance Data	Static and dynamic axial compression, static and dynamic compression shear, and static torsion were completed following ASTM F2077-14. Subsidence was tested following ASTM F2267-04. Expulsion was tested following a recognized protocol to allow comparison evaluation of intervertebral body fusion device assemblies, and characterize their resistance to expulsion. Abrasion testing was performed per ASTM F1978. Additionally, bone graft volume as compared to the predicate and SEM characterization were conducted. The above pre-clinical testing on the Subject device indicate that the Medussa-PL Cage is substantially equivalent to the predicate device.

Conclusion	The Medussa-PL Cage and its predicate have the same intended use, to provide mechanical stability in the lumbar disc space to facilitate biologic fusion. The indications for use of the Medussa-PL Cage are identical to the predicate. The Subject device is similar in size as its predicate. Minor differences between the Subject and predicate devices do not raise any new questions of safety or efficacy. Bench testing demonstrated that the differences do not adversely impact device mechanical performance. Based on the intended use, indications for use, technological characteristics, materials, and comparison to predicate devices, the Subject Medussa-PL Cage (Subject device) has been shown to be substantially equivalent to legally marketed predicate devices.