June 18, 2020

Medyssey USA, Inc.
% Justin Eggleton
Vice President, Spine Regulatory Affairs
MCRA, LLC
1050 K Street NW, Suite 1000
Washington, District of Columbia 20001

Re: K200283
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: March 29, 2020
Received: April 29, 2020

Dear Mr. Eggleton:

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,

Brent Showalter, Ph.D.
Acting 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K200283

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.

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

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5. 510(k) Summary

Device Trade Name: Medussa-PL Cage

Manufacturer:
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Elk Grove Village, IL 60007, USA
Phone: (847) 427-0200

Contact:
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Prepared by:
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Date Prepared: February 4, 2020

Classifications: 21 CFR §888.3080, Intervertebral body fusion device

Class: II

Product Codes: MAX

Primary Predicate: The subject devices are substantially equivalent to the Medyssey Medussa-PL Cage (K170341).

Indications for Use 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.

Device Description:
The Medyssey, Medussa-PL Cage is an interbody fusion device utilized to facilitate the fusion process in the lumbar spine. The cage is additively manufactured from titanium alloy

(ASTM F136 and ASTM F3001) and is available in a range of sizes to accommodate different patient anatomies and pathologies.

Performance Testing Summary:
Engineering CAD analyses including a comparison of device dimensions and materials concluded that based on the similarities in device design, the subject and predicate devices are substantially equivalent with respect to performance since both products have the same dimensions, material, area and bone graft lumen capacity.

Substantial Equivalence:
The subject Medussa-PL Cage is substantially equivalent to the primary predicate, the Medussa-PL Cage (K170341), with respect to indications, design, materials, function, and performance.