



Medyssey USA, Inc.  
% Justin Eggleton  
Senior Director, Spine Regulatory Affairs  
Musculoskeletal Clinical Regulatory Advisers, LLC  
1050 K Street NW, Suite 1000  
Washington, District of Columbia 20001

December 8, 2017

Re: K172756  
Trade/Device Name: Varian cage  
Regulation Number: 21 CFR 888.3080  
Regulation Name: Intervertebral Body Fusion Device  
Regulatory Class: Class II  
Product Code: MAX  
Dated: September 11, 2017  
Received: September 14, 2017

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. 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](mailto:DICE@fda.hhs.gov)) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Katherine D. Kavlock -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

Form Approved: OMB No. 0910-0120  
Expiration Date: 06/30/2020  
See PRA Statement below.

## Indications for Use

510(k) Number (if known)

K172756

Device Name

Varian cage

Indications for Use (Describe)

The Varian cage is indicated for intervertebral body fusion of the lumbar spine, from L2 to S1, in skeletally mature patients who have had six months of non-operative treatment. The device is intended for use at either one level or two contiguous levels for the treatment of degenerative disc disease (DDD) with up to Grade I spondylolisthesis. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies.

Varian cage is designed to be implanted bi-laterally via a posterior (PLIF) approach. The device is intended for use with supplemental fixation and is intended for use with autograft to facilitate fusion.

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

**Device Trade Name:** Varian cage

**Manufacturer:** Medyssey, Co., Ltd.  
1550 E. Higgins Road, Suite 123  
Elk Grove Village, IL 60007, USA  
Phone: (847) 427-0200

**Contact:** Mr. Shawn Kim  
Director  
Medyssey USA, Inc.  
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**Prepared by:** Mr. Justin Eggleton  
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**Date Prepared:** December 4, 2017

**Classification:** 21 CFR §888.3080, Intervertebral body fusion device

**Class:** II

**Product Codes:** MAX

**Primary Predicate Device:** Wenzel Spine, Inc., VariLift®-L Interbody Fusion Device (K151900)

**Additional Predicates:** CoAlign Innovations AccuLIF TL and PL Cage (K132505, K093669)  
Medyssey BN Cage (K140564)  
INNESIS PEEK TL Cage (K140577)  
Medyssey LT Cage (K121246)

**Indications For Use:** The Varian cage is indicated for intervertebral body fusion of the lumbar spine, from L2 to S1, in skeletally mature patients who have had six months of non-operative treatment. The device is intended for use at either one level or two contiguous levels for the treatment

of degenerative disc disease (DDD) with up to Grade I spondylolisthesis. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies.

Varian cage is designed to be implanted bi-laterally via a posterior (PLIF) approach. The device is intended for use with supplemental fixation and is intended for use with autograft to facilitate fusion.

**Device Description:** The Medyssey Varian cage is an interbody fusion device utilized to achieve fusion in the lumbosacral spine. The system is made of titanium alloy and includes seven sizes, ranging from 9 mm to 15 mm in height and 24 mm or 27mm in length with 8° or 10° lordotic angle versions.

**Predicate Device:** Varian cage was shown to be substantially equivalent to previously cleared predicate devices and has the same indications for use, design, function, and materials used. These devices are the Wenzel Spine VariLift®-L Interbody Fusion Device (K151900), CoAlign AccuLIF TL and PL Cage (K132505), Medyssey BN Cage (K140564), INNESIS PEEK TL Cage (K140577), and Medyssey LT Cage (K121246)

**Performance Testing:** Testing performed on this includes FEA worst case verification, Static Compression, Static Compression-Shear, Dynamic Compression, Dynamic Compression-Shear, Subsidence and Expulsion Testing. Testing was performed in accordance with ASTM F2077 and ASTM F2267. Each of these studies were designed to address risks and demonstrate substantially equivalent performance to predicate devices.

**Substantial Equivalence:** The subject Varian cage is substantially equivalent to the primary predicate, the Wenzel Spine VariLift®-L Interbody Fusion Device (K151900), and the additional predicates CoAlign AccuLIF TL and PL Cage (K132505), Medyssey BN Cage (K140564), INNESIS PEEK TL Cage (K140577), and Medyssey LT Cage (K121246) with respect to indications, design, materials, function, and performance.

**Conclusion:** The Varian cage is substantially equivalent to predicate devices with respect to safety and effectiveness.