September 13, 2021

JMT Co., Ltd
Priscilla Chung
Regulatory Affairs Consultant
LK Consulting Group USA, Inc.
1150 Roosevelt STE 200
Irvine, California 92620

Re: K201793
Trade/Device Name: EDEN Peek Cage
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: ODP, MAX
Dated: July 13, 2021
Received: July 15, 2021

Dear Priscilla Chung:

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,

for
Brent Showalter, Ph.D.
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)*
K201793

Device Name
EDEN Peek Cage

Indications for Use *(Describe)*

The EDEN Peek Cage - PLIF Type is indicated for intervertebral body fusion procedures 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. These DDD patients may also have up to Grade 1 spondylolisthesis or retrolisthesis at the involvedlevel(s).This device is to be used with autogenous bone graft. The EDEN Peek Cage System is to be used with supplemental fixation. Patients should have at least six (6) months of non-operative treatment prior to treatment with an intervertebral cage.

The EDEN Peek Cage - ACIF Type is indicated for intervertebral body fusion in skeletally mature patients with degenerative disc disease (DDD) of the cervical spine with accompanying radicular symptoms at one disc level from the C2-C3 disc to the C7-T1 disc. DDD is defined as discogenic pain with degeneration of the disc confirmed by history and radiographic studies. The device system is designed for use with supplemental fixation and with autograft to facilitate fusion. Patients should have at least six weeks of non-operative treatment prior to treatment with an intervertebral cage.

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

(K201793)

This summary of 510(K) information is being submitted in accordance with requirements of 21 CFR Part 807.92.

Date: 9/3/2021

1. Submitter

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2. U.S Agent/Contact Person

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3. Device

- Trade Name: EDEN Peek Cage
- Common Name: Intervertebral Body Fusion System
- Classification:
  - Product Code: ODP (888.3080, Intervertebral Fusion Device With Bone Graft, Cervical, Class II, 510k)
  - Product Code: MAX (888.3080, Intervertebral Fusion Device With Bone Graft, Lumbar, Class II, 510k)

4. Predicate Devices:

- LnK Lumbar Interbody Fusion Cage System by L&K BIOMED Co., Ltd.
- (K181380) Velofix^{TM} Interbody Fusion System by U & I Corporation (K171749)

5. Device Description:

The EDEN Peek Cage is offered in various device configurations based on based on surgical approach and patient anatomy, and consist of:

Cervical Interbody Fusion Device (ACIF Type) which may be implanted as a single device via an anterior approach.

Lumbar Interbody Fusion Device (PLIF Type) which can be implanted Bi-laterally via a posterior approach.

- As a single device via an Anterior approach;(ACIF Type)
- Bi-laterally via a posterior approach;(PLIF Type)

The EDEN Peek Cage is made of polyether ether ketone (VESTAKEEP® i4 R) that conforms to ASTM F2026 and they have tantalum markers (ASTM F560) to assist the surgeon for proper placement of the device. The subject devices are offered gamma sterile.

6. Indication for use:

The EDEN Peek Cage - PLIF Type is indicated for intervertebral body fusion procedures 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. These DDD patients may also have up to Grade 1 spondylolisthesis or retrolisthesis at the involved level(s).This device is to be used with autogenous bone graft. The EDEN Peek Cage System is to be used with supplemental fixation. Patients should have at least six (6) months of non-operative treatment prior to treatment with an intervertebral cage.

The EDEN Peek Cage - ACIF Type is indicated for intervertebral body fusion in skeletally mature patients with degenerative disc disease (DDD) of the cervical spine with accompanying radicular symptoms at one disc level from the C2-C3 disc to the C7-T1 disc. DDD is defined as discogenic pain with degeneration of the disc confirmed by history and radiographic studies. The device system is designed for use with supplemental fixation and with autograft to facilitate fusion. Patients should have at least six weeks of non-operative treatment prior to treatment with an intervertebral cage.

7. Basis for Substantial Equivalence

The subject device is substantially equivalent to LnK Lumbar Interbody Fusion Cage System (K181380) by L&K BIOMED Co., Ltd. and VelofixTM Interbody Fusion System (K171749) by U & I Corporation.

They have the same indications for use and use the same materials with very similar designs. We have conducted the performance tests and the results support that the subject device is substantially equivalent to the predicate devices.

8. Non-Clinical Testing

- Sterilization validating testing has been performed in accordance with ISO 11137
- 36-month shelf life validation
- Mechanical test (static and dynamic axial compression, static and dynamic torsion per ASTM F2077 and subsidence per ASTM F2267)

9. Conclusion

The subject device and the predicate devices have the same intended use and have the same technological characteristics. Based on the similarities and the test results, we conclude that the EDEN Peek Cage is substantially equivalent to the predicate devices.