L&K BIOMED Co., Ltd.
Jihyeon Seo
RA Associate
#201, 202, 16-25, Dongbaekjungang-ro 16 beon-gil,
Giheung-gu, Yongin-si, Gyeonggi-do, 17015
Korea

September 11, 2018

Re: K181380
Trade/Device Name: LnK Lumbar Interbody Fusion Cage System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: MAX
Dated: August 23, 2018
Received: August 23, 2018

Dear Ms. Seo:

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,

Brent Showalter -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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K181380

Device Name
LnK Lumbar Interbody Fusion Cage System

Indications for Use *(Describe)*
LnK Lumbar Interbody Fusion Cage System 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. LnK Lumbar Interbody Fusion 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.

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

The following 510(k) summary is being submitted as required by 21 CFR 807.92(a):

1. Submitter:

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FAX .82-2-6717-1949

Contact Person: Jihyeon Seo

Date prepared: August 28, 2018

2. Device Identification

Trade Name	LnK Lumbar Interbody Fusion Cage System
Common Name	Lumbar Interbody Fusion Cage System
Product Code	MAX
Regulatory Class	II
Classification Name	Intervertebral body fusion device (21 CFR 888.3080)

3. Predicate or legally marketed devices which are substantially equivalent

The design feature and indications for use for the subject LnK Lumbar Interbody Fusion Cage System is substantially equivalent to the following predicates:

- Unmodified device (predicate): LnK Lumbar Interbody Fusion Cage System (K151140)

4. Description of the Device

The LnK Lumbar Interbody Fusion Cage System is intervertebral body fixation devices intended for use as an aid in spinal fixation. This system is fabricated and manufactured from PEEK-OPTIMA® LTl as described by ASTM F2026. The Tantalum marker used for this product is made to the voluntary standard of ASTM F560. The devices are available in a variety of different sizes and heights to match more closely the patient's anatomy. The ends of the implants have machined teeth which are designed to engage with the vertebral body end plates. LnK Lumbar Interbody Fusion Cage System Implants are single-use devices. They have to be used in a healthcare setting or a hospital.

The LnK PLIF PEEK Cages are to be implanted via posterior approach. Two PLIF PEEK cages are placed on each side of the interbody space (right and left).

The LnK T-PLIF PEEK Cages which is used in transforaminal posterior lumbar interbody fusion technique. One T-PLIF cage is implanted in interbody space.

The LnK TLIF PEEK Cages are a "banana" shaped. Implants are dedicated to transforaminal approach. TLIF technique involves placing only one bone graft spacer in the middle of the interbody space, without retraction of the spinal nerves.

The LnK ALIF PEEK Cages are to be implanted via anterior approach.

The LnK DLIF PEEK Cages (LnK LLIF PEEK Cages/LnK Lateral PEEK Cages) are to be implanted via direct lateral interbody fusion approach. LnK DLIF PEEK Cage (LnK LLIF PEEK Cage/LnK Lateral PEEK Cage) can be used in an open approach and a percutaneous approach with MIS instrumentation.

The LnK ATP PEEK Cages are to be implanted via anterior lateral approach.

5. Indication for use

LnK Lumbar Interbody Fusion Cage System 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. LnK Lumbar Interbody Fusion 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.

6. Comparison of the technology characteristics of the device to predicate and legally marketed devices

No	Item	Subject device	Predicate device
		LnK Lumbar Interbody Fusion Cage System	LnK Lumbar Interbody Fusion Cage System
1	Manufacturer	L&K BIOMED Co., Ltd.	L&K BIOMED Co., Ltd.
2	Material	PEEK and Tantalum	PEEK and Tantalum
3	510(K) Number	-	K151140
4	Product Code	MAX	MAX
5	Class	Class Ⅱ	Class Ⅱ
6	Sterility	Non-sterile, Sterile	Non-sterile
7	Intended Use	LnK Lumbar Interbody Fusion Cage System 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. LnK Lumbar Interbody Fusion 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.	LnK Lumbar Interbody Fusion Cage System 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. LnK Lumbar Interbody Fusion 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.

		Current	Previous
		PLIF, T-PLIF, TLIF, ALIF, DLIF, ATP PEEK Cage Width: 11~65mm Length: 11~33mm Height: 6~19mm Lordosis: 0˚~ 30˚	PLIF, T-PLIF, TLIF, ALIF, DLIF Cage Width: 11~65mm Length: 11~32mm Height: 6~19mm Lordosis : 0°~ 14°

7. Performance Data

Mechanical performance of additional components is same with the predicate device (K151140). We performed finite element analysis to demonstrate that the additional components do not introduce a new worst case in terms of mechanical performance. Therefore, we leveraged the mechanical test data of the primary predicate (LnK Lumbar Interbody Fusion Cage System, K151140) to demonstrate the performance of the subject components. It is widely known that gamma sterilization does not affect the performance of the device. Therefore, only mechanical test data of non-sterilized cages was provided.

The LnK Lumbar Interbody Fusion Cage System was tested according to the relevant standards, specifically, Static and Dynamic Axial Compression, Static and Dynamic Compression-Shear Testing, Static and Dynamic Torsion Testing per ASTM F2077, Static Subsidence testing under Axial Compression, per ASTM F2267, and Expulsion Testing and .

8. Conclusion

The additional components of LnK Lumbar Interbody Fusion Cage System are as safe, as effective and perform as well as the predicate device. Therefore, the additional components of LnK Lumbar Interbody Fusion Cage System are substantially equivalent to the predicate device (K151140).