March 9, 2022

L&K BioMed Co., Ltd.
Kang-Keun Lee
Director of Regulatory Affairs
#101, 201, 202 16-25, Dongbaekjungang-ro 16 beon-gil, Giheung-gu
Yongin-si, Gyeonggi-do 17015
South Korea

Re: K213441
Trade/Device Name: PathLoc 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: January 25, 2022
Received: January 28, 2022

Dear Kang-Keun Lee:

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)*
K213441

Device Name
PathLoc Lumbar Interbody Fusion Cage System

Indications for Use *(Describe)*
PathLoc 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 and/or allogenous bone graft composed of cancellous and/or corticocancellous bone. PathLoc 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:

1 Manufacturer

Submitter:	Keun Ju Park L&K BIOMED Co., Ltd.
	#101, 201, 202 16-25, Dongbaekjungang-ro 16 beon-gil Giheung-gu, Yongin-si, Gyeonggi-do, 17015, Korea Phone. 82-2-6717-1983/ FAX .82-2-6717-1949
Date Prepared	October 7, 2020
Contact Person:	Kang-Keun Lee kangkeun.lee@lnkbiomed.com/ ra@lnkbiomed.com

2. Device Identification

Trade Name:	PathLoc Lumbar Interbody Fusion Cage System
Common Name:	Intervertebral Body Fusion Device
Product Code:	MAX
Classification:	Class II
Classification Name:	Intervertebral body fusion device
Regulation No.	21 CFR 888.3080
Classification Pane	Orthopedic

3. Predicate or legally marketed devices which are substantially equivalent.

The PathLoc Lumbar Interbody Fusion Cage System is undergone a comprehensive battery of non-clinical testing, including chemical and physical testing. The PathLoc Lumbar Interbody Fusion Cage System met all pre-defined acceptance criteria and, in tests where it was compared to either PathLoc Lumbar Interbody Fusion Cage System the predicate or reference device, was found to not represent a new worst case. Overall, the results of the performance bench tests support the substantial equivalence of the Subject device.

The design feature, materials, intended use, operational principles and indications for use for the subject device 'PathLoc Lumbar Interbody Fusion Cage System' is substantially equivalent to the following predicate(s);

1) Primary Predicate Device: RISE® Spacer (K113447)
2) Additional Predicate Devices:
   - LnK Lumbar Interbody Fusion Cage System (K110783, K120063, K121096, K151140, K181380)

The subject and predicate devices are substantially equivalent in the areas of materials, design, indications for use, intended use and operational principles.

4 Materials

PathLoc Lumbar Interbody Fusion Cage System is manufactured from Ti-6Al-4V ELI titanium alloy (ASTM F136). This this is the same material used in the predicate devices.

5. Description of the Device

The PathLoc Lumbar Interbody Fusion Cage System implants are interbody fusion devices intended for use as an aid in spinal fixation. They are made of Titanium 6AL-4V Alloy (ASTM F136). These hollow, rectangular implants are offered in a variety of widths, lengths, heights and lordotic angles designed to adapt to a variety of patient anatomies. The implants can be expanded in height after insertion in the unexpanded state using the system instrumentation. The implants have serrations on the superior and inferior surfaces designed for fixation.

- PathLoc - TM is to be implanted via transforaminal and posterior approach.

6. Intended use

PathLoc 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 and/or allogenous bone graft composed of cancellous and/or corticocancellous bone. PathLoc Lumbar Interbody Fusion 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.

7. Performance –Bench testing

The PathLoc Lumbar Interbody Fusion Cage System was tested according to the ASTM F 2077, ASTM F 2267

Static compression, dynamic compression, static and dynamic shear testing according to ASTM F2077, was presented to demonstrate the substantial equivalency of the PathLoc Lumbar Interbody Fusion Cage System to the predicate devices.

- Static Axial Compression Test – ASTM F 2077 -18
- Static Compression-Shear Test - ASTM F 2077 -18
- Static Torsion Test - ASTM F 2077 -18
- Static Subsidence Test – ASTM F 2267 − 04 (Reapproved 2018)/F 2077-18
- Dynamic Axial Compression Test– ASTM F 2077 -18
- Dynamic Compression-Shear Test - ASTM F 2077 -18

Bench testing to evaluate the mechanical properties of the PathLoc Lumbar Interbody Fusion Cage System showed a higher or similar mechanical value than predicate marketed devices.

8. Summary of Technology Characteristics

PathLoc Lumbar Interbody Fusion Cage System is substantially equivalent to the predicate systems in terms of design, materials, indications for use and sizing.

9. Biocompatibility

The device is made of Titanium 6AL-4V Alloy conforming ASTM F136 and is manufactured in an identical manner to the predicate device.

10. Substantial Equivalence:

PathLoc Lumbar Interbody Fusion Cage System was shown to be substantially equivalent to the predicate devices in indications for use, design, function, materials used and mechanical performance.

11. Conclusion

The information presented demonstrates the substantial equivalency of the PathLoc Lumbar Interbody Fusion Cage System to the predicate devices.