January 13, 2023

L&K Biomed Co., Ltd.
Katherine Kim
RA
101, 201, 202 16-25, Dongbaekjungang-ro16 beon-gil Giheung-gu
Yongin-si, Gyeonggi-do 17015
Korea

Re: K223474
Trade/Device Name: PathLoc-TA Expandable Lumbar Cage System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: MAX
Dated: November 15, 2022
Received: November 18, 2022

Dear Katherine Kim:

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,

Katherine D. Kavlock -S

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K223474

Device Name
PathLoc-TA Expandable Lumbar Cage System

Indications for Use *(Describe)*

PathLoc-TA Expandable Lumbar Cage System is indicated for intervertebral body fusion of the spine in skeletally mature patients. The device system is designed for use with bone graft (autograft bone and/or allogenic bone graft composed of cancellous and/or corticocancellous bone graft) to facilitate fusion. PathLoc-TA Expandable Lumbar Cage System is intended for use at either one level or two contiguous levels in the lumbar spine, from L2 to S1, for the treatment of degenerative disc disease (DDD) with up to Grade I spondylolisthesis or retrolisthesis at the involved level(s). DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. Patients should have at least six months of non-operative treatment prior to treatment with a lumbar intervertebral fusion device. The device is intended to be used with supplemental fixation systems that have been cleared for use in the lumbosacral spine (e.g., posterior pedicle screw and rod systems, anterior plate systems, and anterior screw and rod systems).
Hyperlordotic interbody devices (≥20° lordosis) must be used with at least anterior supplemental fixation.

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.

510(k) SUMMARY

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

1. SUBMITTER

Submitter's Name:	L&K BIOMED Co., Ltd.
Submitter's Address:	#201, 202 16-25, Dongbaekjungang-ro 16 beon-gil Giheung-gu, Yongin-si, Gyeonggi-do, 17015, Korea
Submitter's Telephone:	+82-2-6717-1983
Contact Person:	Katherine Kim khkim@lnkbiomed.com / ra@lnkbiomed.com

2. DEVICE NAME

Trade or Proprietary Name	PathLoc-TA Expandable Lumbar Cage System
Common or Usual Name	Intervertebral Body Fusion Device, Intervertebral cage, Spacer
Regulation class / Number	ClassII, CFR 888.3080
Regulation Name	Intervertebral Body Fusion Device
Product Code	MAX
Classification Panel	Spinal Devices (DHT6B)

3. PREDICATE DEVICE

The subject PathLoc-TA Expandable Lumbar Cage System is substantially equivalent to the following devices:

Primary Predicate Device: ABTross ALIF Expandable Lumbar Cage System(K221719)

4. DESCRIPTION OF THE DEVICE

The PathLoc-TA Expandable Lumbar Cage System is interbody fusion devices. This cage system is made of Titanium 6AL-4V Alloy (ASTM F136). And cages are offered in a variety of widths, lengths, heights and lordotic angles designed to adapt to a variety of patient anatomies.

The cage can be expanded in height using the system instrument after being inserted in the unexpanded state. The cages have serrations on the superior endplate and inferior endplate surfaces area to contact vertebrae bone endplate. The device system is designed for use with bone graft (autograft bone and/or allogenic bone graft composed of cancellous and/or corticocancellous bone graft) to facilitate fusion. The device is intended to be used with supplemental fixation systems that have been cleared for use in the lumbrosacral spine (e.g., posterior pedicle screw and rod systems, anterior or lateral plate systems, and anterior screw and rod systems). All implants are provided sterile and intended for SINGLE USE ONLY and should not be reused under any circumstances.

5. INDICATION FOR USE

PathLoc-TA Expandable Lumbar Cage System is indicated for intervertebral body fusion of the spine in skeletally mature patients. The device system is designed for use with bone graft (autograft bone and/or allogenic bone graft composed of cancellous and/or corticocancellous bone graft) to facilitate fusion. PathLoc-TA Expandable Lumbar Cage System is intended for use at either one level or two contiguous levels in the lumbar spine, from L2 to S1, for the treatment of degenerative disc disease

(DDD) with up to Grade I spondylolisthesis or retrolisthesis at the involved level(s). DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. Patients should have at least six months of non-operative treatment prior to treatment with a lumbar intervertebral fusion device. The device is intended to be used with supplemental fixation systems that have been cleared for use in the lumbosacral spine (e.g., posterior pedicle screw and rod systems, anterior plate systems, and anterior screw and rod systems). Hyperlordotic interbody devices (≥20° lordosis) must be used with at least anterior supplemental fixation.

6. PERFORMANCE DATA

Performance testing was performed to demonstrate that the subject PathLoc-TA Expandable Lumbar Cage System is substantially equivalent to other predicate devices.

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

- Static Axial Compression Test – ASTM F 2077 -18
- Static Compression-Shear Test - ASTM F 2077 -18
- Static Expulsion Test - ASTM draft F-04.25.02.02
- Static Subsidence Test – ASTM F 2267 − 04 (Reapproved 2018)
- 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-TA Expandable Lumbar Cage System showed a higher or similar mechanical value than predicate marketed devices.

7. MATERIAL

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

8. COMPARISON OF TECHNICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The subject and predicate devices have identical technological characteristics and there is not any new issues of safety and effectiveness. the following characteristics are same between the subject and predicates:

- Instruction for use
- Design and sizes
- Expanding Mechanism
- Material
- Approach
- Sterilization & Method
- Manufacturing process

9. SUBSTANTIAL EQUIVALENCE AND CONCLUSION

The subject PathLoc-TA Expandable Lumbar Cage System have been found to be substantially equivalent to the predicate devices with respect to technical characteristics, performance, and intended use. The information provided within this premarket notification supports substantial

equivalence of the subject device to the predicate devices.

The overall data lead to the conclusion that the PathLoc-TA Expandable Lumbar Cage System is substantially equivalent to the predicate devices.