October 23, 2024

L&K BIOMED Co., Ltd.
Ms. Kihyang Kim
Vice Chairman
#101, 201, 202 16-25, Dongbaekjungang-ro 16 beon-gil, Giheung-gu
Yongin-si, Gyeonggi-do 17015
South Korea

Re: K242829
Trade/Device Name: BluEX Lumbar Expandable Cage System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: MAX
Dated: September 18, 2024
Received: September 19, 2024

Dear Ms. 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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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)*
K242829

Device Name
BluEX Lumbar Expandable Cage System

Indications for Use *(Describe)*
BluEX Lumbar Expandable 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.
BluEX Lumbar Expandable Cage System is intended for use at either one or two contiguous levels in the lumbar spine, from L1 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 BluEX Lumbar Expandable Cage System must be used with supplementary internal spinal fixation system that are cleared by the FDA for use in the lumbar spine. 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.

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510(k) #: **510(k) Summary** Prepared on: 2024-10-22

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	L&K BIOMED Co., Ltd.
Applicant Address	#101, 201, 202 16-25, Dongbaekjungang-ro 16 beon-gil Giheung-gu, Yongin-si Gyeonggi-do 17015 Korea, South
Applicant Contact Telephone	82-10-5477-0325
Applicant Contact	Ms. Kihyang Kim
Applicant Contact Email	khkim@lnkbiomed.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	BluEX Lumbar Expandable Cage System
Common Name	3080 -Intervertebral body fusion device
Classification Name	Intervertebral Fusion Device With Bone Graft, Lumbar
Regulation Number	21 CFR 8
Product Code(s)	MAX

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K213441	PathLoc Interbody Fusion Cage System	MAX
K223474	PathLoc-TA Expandable Lumbar Cage System	MAX
K231680	AccelFix Lumbar Expandable cage System	MAX
K131612	AnyPlus Peek Cage	MAX

Device Description Summary

21 CFR 807.92(a)(4)

The BluEX Lumbar Expandable Cage System is an interbody fusion device. This cage system is made of Titanium 6AL-4V Alloy (ASTM F136). And the cages are offered in a variety of widths, lengths, heights and lordotic angles designed to adapt to a variety of patient anatomies.
This product consists of BluEX-T, BluEX-TC, BluEX-ATP, BluEX-L, BluEX-LT and BluEX-A which are classified by surgical approach (refer to below table 1. BluEX Lumbar Expandable Cage System)
The cage can be expanded in height using the system instrumentation after being inserted in the unexpanded state. The cages have serrations on the superior and inferior surfaces designed for fixation.
The BluEX Lumbar Expandable Cage System allows packing autograft bone graft and/or allogeneic bone graft composed of cancellous and/or corticocancellous bone to help promote fusion. All implants are provided sterile and intended for SINGLE USE ONLY and should not be reused under any circumstance.
Surgical approach
• BluEX-T is to be implanted via transforaminal and posterior approach.
• BluEX-TC is to be implanted via transforaminal and posterior approach.
• BluEX-ATP is to be implanted via anterior to psoas approach and lateral approach.
• BluEX-L is to be implanted via direct lateral approach.

• BluEX-LT is to be implanted via direct lateral approach.
• BluEX-A is to be implanted via anterior approach.

Intended Use/Indications for Use 21 CFR 807.92(a)(5)

BluEX Lumbar Expandable 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.
BluEX Lumbar Expandable Cage System is intended for use at either one or two contiguous levels in the lumbar spine, from L1 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 BluEX Lumbar Expandable Cage System must be used with supplementary internal spinal fixation system that are cleared by the FDA for use in the lumbar spine. Hyperlordotic interbody devices (≥20° lordosis) must be used with at least anterior supplemental fixation.

Indications for Use Comparison 21 CFR 807.92(a)(5)

The subject BluEX Lumbar Expandable Cage System have been found to be substantially equivalent to the predicate devices with respect to technical characteristics, performance, material 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 BluEX Lumbar Expandable Cage System is substantially equivalent to the predicate devices.

Technological Comparison 21 CFR 807.92(a)(6)

The BluEX Lumbar Expandable Cage System is undergone a comprehensive battery of non-clinical testing, including chemical, physical. Testing has provided reasonable assurance of safety and effectiveness for its intended use and supports a determination of substantial equivalence. The design feature, indications for use the subject devices are substantially equivalent to the predicate devices.

Primary Predicate Device: PathLoc Lumbar Interbody Fusion Cage System(K213441)
Additional Predicate Device: PathLoc-TA Expandable Lumbar Cage System(K223474)
AccelFix Lumbar Expandable Cage System(K231860)
AnyPlus Peek Cage(K131612)

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

Non-Clinical and/or Clinical Tests Summary & Conclusions 21 CFR 807.92(b)

Recognition No. 11-347 ASTM F2077-18 Test Methods for Intervertebral Body Fusion Devices
Recognition No. 11-185 ASTM F2267-04 (Reapproved 2018) Standard Test Method for Measuring Load Induced Subsidence of Intervertebral Body Fusion Device Under Static Axial Compression

N/A

Mechanical test (performance test)
The results of these mechanical tests were found to be equivalent to or higher than the acceptable criteria compared to the predicate devices PathLoc Lumbar Interbody Fusion Cage System (K213441) for Static and Dynamic Compression and shear test and ANYPLUS ALIF PEEK CAGES, PLIF PEEK CAGES, T-PLIF PEEK CAGES, TLIF PEEK CAGES (K131612) for subsidence value as stated in the Acceptable criteria. In addition, the dynamic tests were conducted and the weight and height changes observed at regular intervals were confirmed to be unchanged. Therefore, this test report concludes that the BluEX Lumbar Expandable Cage system has mechanical safety.