August 18, 2026

L&K BIOMED Co., Ltd.
Kihyang Kim
Vice Chairman
#101, 201, 202 16-25, Dongbaekjungang-Ro 16 Beon-Gil
Giheung-Gu,
Yongin-Si, Gyeonggi-do 17015
Republic Of Korea

Re: K262489
Trade/Device Name: BluEX Cervical Expandable Cage System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: ODP
Dated: July 20, 2026
Received: July 20, 2026

Dear Kihyang 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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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,

BRENT SHOWALTER -S

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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.

K262489

Please provide the device trade name(s).

BluEX Cervical Expandable Cage System

Please provide your Indications for Use below.

The BluEX Cervical Expandable Cage System is indicated for intervertebral body fusion of the spine in skeletally mature patients. The BluEX Cervical Expandable Cage System is intended for use in anterior cervical interbody fusion in patients with cervical disc degeneration and/or cervical spinal instability, as confirmed by imaging studies (radiographs, CT, MRI), resulting in radiculopathy, myelopathy, and/or pain at multiple contiguous levels from C2 to T1. The BluEX Cervical Expandable Cage System is designed for use with autogenous and/or allogeneic bone graft comprised of cancellous and/or corticocancellous bone to facilitate fusion. The BluEX Cervical Expandable Cage System is intended to be used with supplemental fixation. Patients should have at least six (6) weeks of non-operative treatment prior to treatment with an intervertebral cage.

Please select the types of uses (select one or both, as applicable).

- [x] Prescription Use (21 CFR 801 Subpart D)
- [ ] Over-The-Counter Use (21 CFR 801 Subpart C)

Please select the age group(s) for which the device(s) is to be used.

- [ ] Neonates/Newborns (Birth to < 29 days old)
- [ ] Infants (29 days old to < 2 years old)
- [ ] Children (2 years old to < 12 years old)
- [ ] Adolescents (12 years old to < 22 years old)
- [x] Adults (22 years old and greater)

510(k) #: K262489

510(k) Summary

Prepared on: 2026-07-20

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, Republic of
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 Cervical Expandable Cage System
Common Name	Intervertebral body fusion device
Classification Name	Intervertebral Fusion Device With Bone Graft, Cervical
Regulation Number	888.3080
Product Code(s)	ODP

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K260840	BluEX Cervical Expandable Cage System	ODP

Device Description Summary

21 CFR 807.92(a)(4)

The BluEX Cervical Expandable Cage System is an expandable intervertebral body fusion device intended for use in the cervical spine to facilitate fusion between adjacent vertebral bodies following discectomy. The device is designed to be inserted into the intervertebral disc space in a collapsed configuration and subsequently expanded in situ to restore disc height and provide structural support during the fusion process.

The cages are manufactured from titanium alloy (Ti-6Al-4V) conforming to ASTM F136, a material commonly used in implantable spinal devices due to its strength, corrosion resistance, and biocompatibility. The device is available in a range of widths, lengths, heights, and lordotic angles to accommodate different patient anatomies and surgical requirements.

The cage can be expanded in height using dedicated system instrumentation after insertion into the intervertebral disc space. The superior and inferior surfaces incorporate serrated features designed to enhance fixation to the vertebral endplates and reduce the potential for implant migration.

The BluEX Cervical Expandable Cage System includes a central graft chamber that allows packing of autogenous bone graft and/or allogeneic bone graft composed of cancellous and/or corticocancellous bone to promote bony fusion between adjacent vertebral bodies.

All implants are provided sterile and are intended for single use only. The implants must not be reused under any circumstances.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

The BluEX Cervical Expandable Cage System is indicated for intervertebral body fusion of the spine in skeletally mature patients. The

BluEX Cervical Expandable Cage System is intended for use in anterior cervical interbody fusion in patients with cervical disc degeneration and/or cervical spinal instability, as confirmed by imaging studies (radiographs, CT, MRI), resulting in radiculopathy, myelopathy, and/or pain at multiple contiguous levels from C2 to T1. The BluEX Cervical Expandable Cage System is designed for use with autogenous and/or allogeneic bone graft comprised of cancellous and/or corticocancellous bone to facilitate fusion. The BluEX Cervical Expandable Cage System is intended to be used with supplemental fixation. Patients should have at least six (6) weeks of non-operative treatment prior to treatment with an intervertebral cage.

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

The subject BluEX Cervical 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 and manufacturing process the subject devices are substantially equivalent to the predicate devices.

Technological Comparison 21 CFR 807.92(a)(6)

Primary Predicate Device: BluEX Cervical Expandable Cage System (K260840)
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)

The BluEX Cervical 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.