March 3, 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
Korea, South

Re: K251940
Trade/Device Name: PathLoc Lumbar Plate System
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal Intervertebral Body Fixation Orthosis
Regulatory Class: Class II
Product Code: KWQ
Dated: February 13, 2026
Received: February 13, 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 13484 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and 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 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 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,

MAZIAR SHAH-MOHAMMADI -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

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.	K251940

Please provide the device trade name(s).

PathLoc Lumbar Plate System

Please provide your Indications for Use below.

The PathLoc Lumbar Plate System is indicated for use via the anterior surgical approach above the bifurcation of the great vessels or via the anterior surgical approach, below the bifurcation of the great vessels as an adjunct to fusion.
This system is indicated in the treatment of lumbar and lumbosacral (L1-S1) spine instability as a result of fracture (including dislocation and subluxation), tumor, degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc conformed by patient history and radiographic studies), pseudoarthrosis, spondylolysis, scoliosis, spondylolisthesis, lordotic deformities of the spine, spinal stenosis, or a failed previous spine surgery.

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

- ☒ Prescription Use (21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

510(k) #: K251940

510(k) Summary

Prepared on: 2026-03-03

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	PathLoc Lumbar Plate System
Common Name	Spinal intervertebral body fixation orthosis
Classification Name	Appliance, Fixation, Spinal Intervertebral Body
Regulation Number	888.3060
Product Code(s)	KWQ

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K192481	AccelFix Lumbar Plate System	KWQ
K173885	Binary® Lumbar Plate System	KWQ
K231839	AccelFix Lumbar Plate System	KWQ
K192678	Binary® Lumbar Plate System	KWQ

Device Description Summary

21 CFR 807.92(a)(4)

The system consists of plates and fixation screws manufactured from titanium alloy (Ti-6Al-4V ELI) in accordance with ASTM F136 standards, and it includes manual surgical instruments commonly used in general surgical procedures.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

The PathLoc Lumbar Plate System is indicated for use via the anterior surgical approach above the bifurcation of the great vessels or via the anterior surgical approach, below the bifurcation of the great vessels as an adjunct to fusion.
This system is indicated in the treatment of lumbar and lumbosacral (L1-S1) spine instability as a result of fracture (including dislocation and subluxation), tumor, degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc conformed by patient history and radiographic studies), pseudoarthrosis, spondylolysis, scoliosis, spondylolisthesis, lordotic deformities of the spine, spinal stenosis, or a failed previous spine surgery.

Indications for Use Comparison

21 CFR 807.92(a)(5)

The subject PathLoc Lumbar Plate 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 Lumbar Plate System is substantially equivalent to the predicate devices.

Technological Comparison

21 CFR 807.92(a)(6)

The design features, materials, intended use, operational principles, and indications for use of the subject device—PathLoc Lumbar Plate System—are substantially equivalent to the following predicate devices:
1) Primary Predicate Device: AccelFix Lumbar Plate System (L&K Biomed, K192481/K231839)
2) Additional Predicate Device: Binary Lumbar Plate System (Genesys Spine, K173885 / K192678)
The subject device and predicate devices are substantially equivalent in terms of materials, design, indications for use, intended use, and operational principles.

Non-Clinical and/or Clinical Tests Summary & Conclusions

21 CFR 807.92(b)

Mechanical testing was conducted to evaluate the mechanical safety of the PathLoc Lumbar Plate System in accordance with ASTM F1717 and the FDA guidance document "Spinal Plating Systems – Performance Criteria for Safety and Performance Based Pathway." The test values of the PathLoc Lumbar Plate System were directly compared with the performance criteria specified in the aforementioned FDA guidance.The mechanical test results demonstrated that the performance of the PathLoc Lumbar Plate System was comparable to or exceeded the acceptance criteria outlined in the "Spinal Plating Systems – Performance Criteria for Safety and Performance Based Pathway" guidance document.Therefore, this test report concludes that the PathLoc Lumbar Plate System meets the mechanical safety requirements.