May 5, 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: K261130
Trade/Device Name: AccelFix Spinal Fixation System
Regulation Number: 21 CFR 888.3070
Regulation Name: Thoracolumbosacral Pedicle Screw System
Regulatory Class: Class II
Product Code: NKB, KWP, KWQ
Dated: April 6, 2026
Received: April 6, 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,

COLIN
O'NEILL -S

Colin O'Neill, M.B.E.
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.	K261130

Please provide the device trade name(s).

AccelFix Spinal Fixation System

Please provide your Indications for Use below.

The AccelFix Spinal Fixation System is a non-cervical spinal fixation device intended for use as a posterior pedicle screw fixation system (T1-S2/ilium), or as an anterolateral fixation system (T8-L5). All components in the system are limited to skeletally mature patients. These devices are indicated as an adjunct to fusion for all of the following indications regardless of the intended use: degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies); spondylolisthesis; trauma (i.e., fracture or dislocation); deformities or curvatures (i.e., scoliosis, kyphosis, and/or lordosis); tumor; stenosis, and failed previous fusion (pseudoarthrosis).

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) #: K261130

510(k) Summary

Prepared on: 2026-05-02

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	AccelFix Spinal Fixation System
Common Name	Thoracolumbosacral Pedicle Screw System
Classification Name	Thoracolumbosacral Pedicle Screw System
Regulation Number	888.3070
Product Code(s)	NKB, KWP, KWQ

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K232311	AccelFix Spinal Fixation System	NKB
K182544	AccelFix Spinal Fixation System	NKB

Device Description Summary

21 CFR 807.92(a)(4)

The AccelFix Spinal Fixation System is a posterior thoracolumbar, sacral, and iliac fixation system intended to provide immobilization, stabilization, and alignment correction of spinal segments as an adjunct to spinal fusion. The system consists of a comprehensive range of pedicle screws, rods, hooks, cross-link, connectors, and associated instruments designed to accommodate varying patient anatomy and pathological conditions. Multiple implant configurations, including monoaxial, polyaxial, reduction, and specialty screw options, are available in various diameters and lengths to address diverse surgical requirements. Implants are typically manufactured from titanium alloy or other biocompatible metallic materials, and threaded implant features are designed to enhance fixation at the bone-implant interface. The system incorporates secure rod capture and fixation mechanisms to create a stable construct for segmental support and correction. It may be utilized in open or minimally invasive surgical approaches depending on procedural requirements. The modular design allows for customized construct assembly based on patient-specific pathology and surgical objectives while supporting load sharing, maintenance of corrective alignment, and fusion

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

The AccelFix Spinal Fixation System is a non-cervical spinal fixation device intended for use as a posterior pedicle screw fixation system (T1-S2/ilium), or as an anterolateral fixation system (T8-L5). All components in the system are limited to skeletally mature patients. These devices are indicated as an adjunct to fusion for all of the following indications regardless of the intended use: degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies); spondylolisthesis; trauma (i.e., fracture or dislocation); deformities or curvatures (i.e., scoliosis, kyphosis, and/or lordosis); tumor; stenosis, and failed previous fusion (pseudoarthrosis).

Indications for Use Comparison

21 CFR 807.92(a)(5)

The indications for use of the subject AccelFix Spinal Fixation System is the same as those of the primary predicate device, AccelFix Spinal Fixation System (K232311).In addition, the intended use of the subject device is also the same as that of the additional predicate device, AccelFix Spinal Fixation System (K182544).Therefore, both the predicate devices and the subject device are intended for use as a posterior pedicle screw fixation system (T1-S2/ilium), or as an anterolateral fixation system (T8-L5). The overall Data lead to the conclusion that the AccelFix Spinal Fixation System is substantially equivalent to the predicate devices.

Technological Comparison

21 CFR 807.92(a)(6)

The additional AccelFix Spinal Fixation System are considered substantially equivalent to the predicate devices. The systems have same design, materials, scientific technology, and indications for use.

Primary Predicate Device: AccelFix Spinal Fixation System (K232311)
Additional Predicate Devices: AccelFix Spinal Fixation System (K182544)

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

Non-Clinical and/or Clinical Tests Summary & Conclusions

21 CFR 807.92(b)

The subject AccelFix Spinal Fixation System was compared with the legally marketed predicate devices, AccelFix Spinal Fixation System (K232311 and K182544), to establish worst-case justification.Mechanical bench testing of the predicate devices was conducted in accordance with ASTM F1717, a standard test method for spinal implant constructs.In addition, an engineering analysis was performed for the subject device, which demonstrated that the design modifications do not represent a worst-case condition relative to the predicate devices. Therefore, no additional performance testing was deemed necessary.Based on these results, the subject device demonstrates substantially equivalent mechanical performance compared to the predicate devices, and the information provided in this 510(k) submission supports a determination of substantial equivalence.