



May 6, 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: K261112
Trade/Device Name: CastleLoc-P Anterior Cervical Plate System
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal Intervertebral Body Fixation Orthosis
Regulatory Class: Class II
Product Code: KWQ
Dated: April 1, 2026
Received: April 3, 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,

STEPHANIE SMITH -S

For: Colin O'Neill, M.B.E.
Acting 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.

K261112

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Please provide the device trade name(s).

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CastleLoc-P Anterior Cervical Plate System

Please provide your Indications for Use below.

?

The CastleLoc-P Anterior Cervical Plate System is intended for anterior screw fixation to the cervical spine (C2-C7). The System is indicated for use in the immobilization and stabilization of the spine as an adjunct to fusions in patients with:

- degenerative disc disease (as defined by neck pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies),
- spondylolisthesis,
- trauma (i.e. fractures or dislocations),
- tumors,
- deformity (defined as kyphosis, lordosis, or scoliosis),
- pseudoarthrosis,
- failed previous fusion,
- spinal stenosis.

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](#))

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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)
- ☒ Adults (22 years old and greater)

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510(k) #: K261112

510(k) Summary

Prepared on: 2026-04-03

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	CastleLoc-P Anterior Cervical 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
K231839	CastleLoc-P Anterior Cervical Plate System	KWQ
K143271	CastleLoc-P Anterior Cervical Plate System	KWQ

Device Description Summary

[21 CFR 807.92\(a\)\(4\)](#)

The CastleLoc-P Anterior Cervical Plate System consists of a variety of plates and screws manufactured from titanium alloy Ti-6Al-4V ELI (ASTM F136).

This system is intended for anterior stabilization of the cervical spine. The implant is designed to immobilize the fusion site until solid bone fusion has occurred following bone grafting.

The device is intended for implantation in the human body and is composed of various configurations of cervical plates. The plates are affixed to the vertebral bodies, and fixation is achieved using screws.

Intended Use/Indications for Use

[21 CFR 807.92\(a\)\(5\)](#)

The CastleLoc-P Anterior Cervical Plate System is intended for anterior screw fixation to the cervical spine (C2-C7). The System is indicated for use in the immobilization and stabilization of the spine as an adjunct to fusions in patients with:

- degenerative disc disease (as defined by neck pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies),
- spondylolisthesis,
- trauma (i.e. fractures or dislocations),
- tumors,
- deformity (defined as kyphosis, lordosis, or scoliosis),
- pseudoarthrosis,
- failed previous fusion,

- spinal stenosis.

Indications for Use Comparison

[21 CFR 807.92\(a\)\(5\)](#)

The indications for use of the subject CastleLoc-P Anterior Cervical Plate System are the same as those of the primary predicate device, CastleLoc-P Anterior Cervical Plate System (K231839). In addition, the intended use of the subject device is also the same as that of the additional predicate device, CastleLoc-P Anterior Cervical Plate System (K143271). Therefore, both the predicate devices and the subject device are intended for anterior screw fixation to the cervical spine (C2–C7), and are indicated for use in the immobilization and stabilization of the spine as an adjunct to fusion. The overall Data lead to the conclusion that the CastleLoc-P Anterior Cervical Plate System is substantially equivalent to the predicate devices.

Technological Comparison

[21 CFR 807.92\(a\)\(6\)](#)

The subject CastleLoc-P Anterior Cervical Plate System includes additional plates and screws with similar dimensions compared to the legally marketed predicate devices, CastleLoc-P Anterior Cervical Plate System (K231839 and K143271). An engineering analysis was performed for the subject CastleLoc-P Anterior Cervical Plate System, which demonstrated that the design modifications of the subject device do not represent a worst-case condition relative to the predicate devices. The design characteristics and indications for use of the subject device system are substantially equivalent to those of the predicate devices. In addition, the subject device and the predicate devices (K231839 and K143271) are the same with respect to materials, manufacturing process, design, indications for use, intended use, and operational principles.

Non-Clinical and/or Clinical Tests Summary & Conclusions

[21 CFR 807.92\(b\)](#)

The subject CastleLoc-P Anterior Cervical Plate System was compared with the legally marketed predicate devices, CastleLoc-P Anterior Cervical Plate System (K231839 and K143271), to confirm worst-case justification. Mechanical bench testing of the predicate CastleLoc-P Anterior Cervical Plate System was conducted in accordance with ASTM F1717, a standard test method for spinal implant constructs. An engineering analysis was also performed for the subject CastleLoc-P Anterior Cervical Plate System, which demonstrated that the design modifications of the subject device do not represent a worst-case condition relative to the predicate devices. Therefore, no additional performance testing was required. Based on these results, the subject CastleLoc-P Anterior Cervical Plate System 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.