July 19, 2023

L & K Biomed Co., Ltd.
Katherine Kim
RA
#101, 201, 202 16-25, Dongbaekjungang-ro 16
beon-gil, Giheung-gu
Yongin-si, Gyeonggi-do 17015
South Korea

Re: K231839
Trade/Device Name: CastleLoc-P Anterior Cervical Plate System, AccelFix Lumbar Plate System
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal Intervertebral Body Fixation Orthosis
Regulatory Class: Class II
Product Code: KWQ
Dated: June 20, 2023
Received: June 22, 2023

Dear Katherine 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 (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 located 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.

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

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

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)*

K231839

Device Name

CastleLoc-P Anterior Cervical Plate System

Indications for Use *(Describe)*

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.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
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Paperwork Reduction Act (PRA) Staff
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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)*

K231839

Device Name

AccelFix Lumbar Plate System

Indications for Use *(Describe)*

The AccelFix Lumbar Plate System is indicated for use via the anterior, lateral or anterolateral 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 confirmed by patient history and radiographic studies), pseudoarthrosis, spondylolysis, scoliosis, spondylolisthesis, lordotic deformities of the spine, spinal stenosis, or a failed previous spine surgery.

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)

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510(k) SUMMARY

The following 510(k) summary is being submitted as required by 21 CFR 807.92(a):

1. MANUFACTURER

Submitter's Name:	L&K Biomed Co., Ltd.
Submitter's Address:	#101, 201, 202 16-25, Dongbaekjungang-ro 16 beon-gil Giheung-gu, Yongin-si, Gyeonggi-do, 17015, Korea.
Submitter's Telephone:	82-2-6717-1983
Contact Person:	Katherine Kim/82-2-6717-1983 khkim@lnkbiomed.com
Prepared Date:	June 20, 2023

2. DEVICE IDENTIFICATION

Device Trade Name	CastleLoc-P Anterior Cervical Plate System
Common/Usual Name	Appliance, Fixation, Spinal Intervertebral Body
Regulation Class /Number	Class II / 21 CFR 888.3060
Regulation Name	Spinal Intervertebral Body Fixation Orthosis
Product Code	KWQ
Classification Panel	Spinal Devices (DHT6B)

Device Trade Name	AccelFix Lumbar Plate System
Common/Usual Name	Lumbar Spinal Plate
Regulation Class /Number	Class II/ 21 CFR 888.3060
Regulation Name	Spinal Intervertebral Body Fixation Orthosis
Product Code	KWQ
Classification Panel	Spinal Devices (DHT6B)

3. PREDICATE OR LEGALLY MARKETED DEVICES WHICH ARE SUBSTANTIALLY EQUIVALENT.

The subject devices are identical to the predicate devices in all characteristics.

Subject Device Name	510K NO.	Trade or Proprietary or Model Name	Predicate Type
CASTLELOC-P Anterior Cervical Plate System	K 143271	CastleLoc-P Anterior Cervical Plate System	Primary
	K113509 K143279 K 190425	LnK Anterior Cervical Plate System	Additional
		LnK Anterior Cervical Plate System	
		CastleLoc-P Anterior Cervical Plate System	
	K 210035 K 223719	Paeon Anterior Plate System	Additional
AccelFix Lumbar Plate System	K 192481	AccelFix Lumbar Plate System	Primary
	K 210035 K 223719	Elatus Lumbar Plate System	Additional

The design feature, indications for use, material and manufacturing process for the subject devices are substantially equivalent to the predicate devices (CastleLoc-P Anterior Cervical Plate System K113509, K143279, K143271, K190425/ AccelFix Lumbar Plate System K192481/200794).

4. MATERIALS- And the additional components material is the same material used in the predicate device**s.**

CastleLoc-P Anterior Cervical Plate System	Ti-6Al-4V ELI titanium alloy (ASTM F136)
AccelFix Lumbar Plate System	Ti-6Al-4V ELI titanium alloy (ASTM F136)

5. DESCRIPTION OF THE DEVICE

The CastleLoc-P Anterior Cervical Plate System is composed of plates, screws and lockers which are made from titanium alloy per ASTM F136. These plates attach to the anterior cervical spine with a minimum of four screws per plate. The plates are offered in one-level, two-level, three-level, four-level fusion configurations (13~97mm). The plate screws are 3.5mm and 4.0mm diameter head screws. They are self-tapping and self-drilling threaded. This device can be provided both as non-sterile and sterile.

The AccelFix Lumbar Plate System's implants are Lumbar Plate System intended for use as an aid in spinal fixation. They are made from titanium alloy per ASTM F136. The AccelFix Lumbar Plate System consists of a variety of shapes and sizes of plates and screws. The plate has been designed to include spikes for added stability and alignment during screw insertion. The plates feature a curvature for anatomic fit. The diameter of screw is available from 5.5 to 6.0 mm and the length from 20 to 55 mm.

6. INDICATION FOR USE

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.

The AccelFix Lumbar Plate System is indicated for use via the anterior, lateral, or anterolateral 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 confirmed by patient history and radiographic studies), pseudoarthrosis, spondylolysis, scoliosis, spondylolisthesis, lordotic deformities of the spine, spinal stenosis, or a failed previous spine surgery.

7. PERFORMANCE TESTING

CastleLoc-P Anterior Cervical Plate System

The additional components to be added through this submission do not require additional mechanical testing. None of the additional components is the worst case of the CastleLoc-P Posterior Anterior Cervical Plate System.

AccelFix Lumbar Plate System

The additional components to be added through this submission do not require additional mechanical testing. None of the additional components is the worst case of the AccelFix Lumbar Plate System.

Therefore, we substitute mechanical test data of CastleLoc-P Anterior Cervical Plate System (predicate devices K113509, K143279, K143271, K190425) and AccelFix Lumbar Plate System (predicate device K 192481) for additional components with the predicate device data.

8. SUMMARY OF TECHNOLOGY CHARACTERISTICS

Subject devices are identical to the predicate devices in all (design feature, indications for use, surgical approach and manufacturing process) characteristics.

CastleLoc-P CastleLoc-P Anterior Cervical Plate System

	510K no.	Indication for use	Design	Surgical approach	Material
Subject Device	-	Same	Similar	Same	Ti-6Al-4V ELI (ASTM F136)
CastleLoc-P Anterior Cervical Plate System	Primary K143271	Same	Similar	Same	Same
LnK Anterior Cervical Plate System CastleLoc-P Anterior Cervical Plate System	K113509 K143279 K190425	Same	Similar	Same	Same
Paeon Anterior Plate System	K210035 K223719	Same	Similar	Same	Same

AccelFix Lumbar Plate System

	510K no.	Indication for use	Design	Surgical approach	Material
Subject Device	-	Same	Similar	Same	Ti-6Al-4V ELI (ASTM F136)
AccelFix Lumbar Plate System	Primary K192481	Same	Similar	Same	Same
Elatus Lumbar Plate System	K210035 K223719	Same	Similar	Same	Same

9. SUBSTANTIAL EQUIVALENCE

Subject devices are shown to be substantially equivalent to the predicate devices in indications for use, design, function, and materials used.

10. CONCLUSION

The overall technology characteristics lead to the conclusion that the CastleLoc-P Anterior Cervical Plate System, and AccelFix Lumbar Plate System is substantially equivalent to the predicate devices (CastleLoc-P Anterior Cervical Plate System K113509, K143279, K143271, K190425/ AccelFix Lumbar Plate System K192481/200794).