July 20, 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: K231840
Trade/Device Name: CastleLoc-S Posterior Cervical Fixation System
Regulation Number: 21 CFR 888.3075
Regulation Name: Posterior Cervical Screw System
Regulatory Class: Class II
Product Code: NKG, KWP
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

FDA

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)*
K231840

Device Name

CastleLoc-S Posterior Cervical Fixation System

Indications for Use *(Describe)*

The CastleLoc-S Posterior Cervical Fixation System is intended to provide immobilization and stabilization of spinal segments as an adjunct to fusion for the following acute and chronic instabilities of the cervical spine (C1 to C7) and the thoracic spine (T1-T3): traumatic spinal fractures and/or traumatic dislocations; instability or deformity; failed previous fusions (e.g., pseudoarthrosis); tumors involving the cervical spine; and degenerative disease, including intractable radiculopathy and/or myelopathy, neck and/or arm pain of discogenic origin as confirmed by radiographic studies, and degenerative disease of the facets with instability. The CastleLoc-S Posterior Cervical Fixation System is also intended to restore the integrity of the spinal column even in the absence of fusion for a limited time period in patients with advanced stage tumors involving the cervical spine in whom life expectancy is of insufficient duration to permit achievement of fusion. The CastleLoc-S Posterior Cervical Fixation System can be linked to the LnK Spinal Fixation System, OpenLoc-L Spinal Fixation System and AccelFix Spinal Fixation System via rod to rod connector and transitional rod.

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.

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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-S Posterior Cervical Fixation System
Common/Usual Name	Spinal Fixation System
Regulation Class /Number	Class II / 21 CFR 888.3075 / 21 CFR 888.3050
Regulation Name	Posterior cervical screw system
Product Code	NKG, KWP
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.

510k Number	Trade or Proprietary or Model Name	Predicate Type
K 143278	LnK Posterior Cervical Fixation System	Primary
K 120879	LnK Posterior Cervical Fixation System	Additional
K 103414	LnK Posterior Cervical Fixation System	
K 162136 K 200793	LnK Posterior Cervical Fixation System and CastleLoc-S Posterior Cervical Fixation System	
K 210035	MegaCerfix(Former name) Posterior Cervical Fixation System	Additional
K 221050	Paeon Posterior Cervical Fixation System	

The design feature, indications for use and manufacturing process for the subject devices are substantially equivalent to the predicate devices.

4. Materials

CastleLoc-S Posterior Cervical Fixation System	Ti-6Al-4V ELI titanium alloy (ASTM F136) and Cobalt-28Chromium-6Molybdenum-4Vanadium ELI (ASTM F1537)

5. Description of the Device

The CastleLoc-S Posterior Cervical Fixation System is a top-loading, multiple components, posterior (cervical-thoracic) spinal fixation system which consists of poly screw, Reduction poly screw, partially screw, semi-reduction partially screw, straight rod, curved rod, set screw, hooks and accessories that can be used via an open surgical approach. The devices are manufactured from titanium alloy per ASTM F136 and cobalt chromium per ASTM F1537.

6. INDICATION FOR USE

The CastleLoc-S Posterior Cervical Fixation System is intended to provide immobilization and stabilization of spinal segments as an adjunct to fusion for the following acute and chronic instabilities of the cervical spine (C1 to C7) and the thoracic spine (T1-T3): traumatic spinal fractures and/or traumatic dislocations; instability or deformity; failed previous fusions (e.g., pseudoarthrosis); tumors involving the cervical spine; and degenerative disease, including intractable radiculopathy and/or myelopathy, neck and/or arm pain of discogenic origin as confirmed by radiographic studies, and degenerative disease of the facets with instability. The CastleLoc-S Posterior Cervical Fixation System is also intended to restore the integrity of the spinal column even in the absence of fusion for a limited time period in patients with advanced stage tumors involving the cervical spine in whom life expectancy is of insufficient duration to permit achievement of fusion. The CastleLoc-S Posterior Cervical Fixation System can be linked to the LnK Spinal Fixation System, OpenLoc-L Spinal Fixation System and AccelFix Spinal Fixation System via rod to rod connector and transitional rod.

7. Performance Testing

The CastleLoc-S Posterior Cervical Fixation System is identical to the predicates; mechanical testing is not required to establish substantial equivalence.

A risk assessment, including ASTM F1717 testing for static compression bending and static torsion mechanical testing, was conducted to confirm that the additional components do not introduce new issues of safety or effectiveness. The additional components to be added through this submission do not require additional mechanical testing. None of the additional sizes is the worst case of the CastleLoc-S Posterior Cervical Fixation System. Therefore, we substitute mechanical test data of additional components of CastleLoc-S Posterior Cervical Fixation System with the predicate device (K103414, K120879, K143278, K162136, K200793).

8. Summary of Technology Characteristics

Subject devices are identical to the predicate devices, material, design, mechanism, indication for use and manufacturing process in all characteristics.

9. Substantial Equivalence

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

	510K no.	Indication for use	Material	Design	Sterilization Method
Subject CastleLoc-S CastleLoc-S Posterior Cervical Fixation System		Similar	Same	Identical device	Same
LnK Posterior Cervical Fixation System and CastleLoc-S Posterior Cervical Fixation System	K103414 K120879 K143278 K162136 K200793	Similar	Same	Identical device	Same
Paeon Posterior Cervical Fixation System	K 210035 K 221050	Similar	Same	Identical device	Same

10. Conclusion

The overall technology characteristics lead to the conclusion that the CastleLoc-S Posterior Cervical Fixation System is substantially equivalent to the predicate devices (K103414, K120879, K143278, K162136, K200793).