April 25, 2025

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

Re: K250892
Trade/Device Name: CastleLoc Pectus Bar System
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/Multiple Component Metallic Bone Fixation Appliances And Accessories
Regulatory Class: Class II
Product Code: HRS
Dated: March 24, 2025
Received: March 25, 2025

Dear Kihayng 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 System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 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 systems (QS) regulation (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,

CHRISTOPHER FERREIRA -S

Christopher Ferreira, M.S.
Assistant Director
DHT6C: Division of Restorative,
Repair, and Trauma 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)*
K250892

Device Name
CastleLoc Pectus Bar System

Indications for Use *(Describe)*
The CastleLoc Pectus Bar System is indicated for the treatment of Pectus Excavatum and other anterior chest deformities. It is intended to be used in pediatric (children and adolescents) and adult populations.

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) #: K250892

510(k) Summary

Prepared on: 2025-04-25

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, South
Applicant Contact Telephone	82-10-5477-0325
Applicant Contact	Mrs. Kihayng Kim
Applicant Contact Email	khkim@lnkbiomed.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	CastleLoc Pectus Bar System
Common Name	Single/multiple component metallic bone fixation appliances and accessories
Classification Name	Plate, Fixation, Bone
Regulation Number	888.3030
Product Code(s)	HRS

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K243357	CastleLoc Pectus Bar System	HRS
K191057	Park's Pectus System	HRS

Device Description Summary

21 CFR 807.92(a)(4)

The Castleloc Pectus Bar System is a thoracic support product that repairs the thoracic wall, using minimally invasive surgical techniques to elevate the ribs and sternum to correct a type of chest wall deformity called pectus excavatum. Recommended implantation time is 2~3 years but may vary based on surgeon preference and patient.

This system includes various sizes of straight and curved Castleloc Pectus Bars. The appropriate bar is selected based on suitability for the patient body size. The Castleloc Pectus Bar, and Castleloc Pectus Stabilizer, Nut and Castleloc Pectus Claw Fixator for fixing the Castleloc Pectus Bar, are made of Ti-6Al-4V (ASTM F136).

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

The CastleLoc Pectus Bar System is indicated for the treatment of Pectus Excavatum and other anterior chest deformities. It is intended to be used in pediatric (children and adolescents) and adult populations.

Indications for Use Comparison

21 CFR 807.92(a)(5)

The subject CastleLoc Pectus Bar System indications for use are the same as the indications for the primary predicate device CastleLoc Pectus Bar System (K243357). The intended use of the subject device is also the same as the additional predicate device Park's Pectus System (K191057) in that they are both intended to treat Pectus Excavatum and other anterior chest wall deformities.

Technological Comparison

21 CFR 807.92(a)(6)

The subject Castleloc Pectus Bar System includes additional pectus bars with various dimensions (both shorter and longer lengths) compared to the legally marketed primary predicate device, Castleloc Pectus Bar System (K243357). The subject device plates are also offered in similar dimensions compared to the additional predicate device, Park's Pectus System (K191057). The design features and indications for use of the subject device system are substantially equivalent to the predicate devices. The subject and primary predicate device (K243357) are also the same with regard 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 Pectus Bar system was compared to the legally marketed primary predicate, K243357 CastleLoc Pectus Bar system, to confirm worst case justification. Mechanical bench testing was conducted per ASTM F382-17 including Static 4-Point Bending, Dynamic (fatigue) 4-Point Bending, and Vertical Tensile Tests. The CastleLoc-Pectus Bar system test values were compared side-by-side to test values of the Park's Pectus System (K1910571). These mechanical test results were shown to be similar or higher than the reference product, Park's Pectus System (K1910571), specified in the acceptance criteria.

Therefore, the additional CastleLoc Pectus Bar system has substantially equivalent mechanical performance as compared to the predicate devices and supports that the device is as safe and effective as the predicate devices. The information provided in this 510(k) submission supports a conclusion of substantial equivalence.