March 21, 2019

L&K BIOMED Co., Ltd.
Ms. Jihyeon Seo
Regulatory Affairs Associate
#201, #202 16-25, Dongbaekjungang-ro 16 beon-gil,
Giheung-gu, Yongin-si, Gyeonggi-do, 17015
KOREA

Re: K190425
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: February 20, 2019
Received: February 22, 2019

Dear Ms. Seo:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Ronald P. Jean -S

for Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K190425

Device Name
CastleLoc-P Anterior Cervical Plate System

Indications for Use *(Describe)*
The 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.

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510(k) SUMMARY

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

1. **Submitter:** L&K BIOMED Co., Ltd.
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Giheung-gu, Yongin-si, Gyeonggi-do, 17015, Korea
Phone: 82-2-6717-1983
e-mail: kate.seo@lnkbiomed.com
Contact Person: Jihyeon Seo
Date prepared February 20th, 2019

2. **Device Identification**

Trade Name	CastleLoc-P Anterior Cervical Plate System
Regulatory Class	Class II
Regulation Name/Common Name	Anterior Cervical Plate
Classification Name	Spinal Intervertebral Body Fixation Orthosis (21 CFR888.3060)
Panel	Orthopedic
Product Code	KWQ

3. **Purpose of 510(k)**
L&K BIOMED Co. Ltd., is submitting this Special 510(k) to add new components to own 510(k)-cleared device (K143271)

4. **The name of the legally marketed (unmodified) device**
■ K143271 CastleLoc-P Anterior Cervical Plate System (primary predicate)

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 Ti-6Al-4V ELI (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 (19~97mm). 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.

6. Indication for Use

The 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.

7. Comparison of the technological characteristics of the subject and predicate devices

The new components of the CastleLoc-P Anterior Cervical Plate System are considered substantially equivalent to the referenced device (K143271). The systems have the same design, material, scientific technology, and indications for use. The only difference is that there are additional components which use different sterilization method (gamma sterilization).

A rationale was provided as to why gamma sterilization does not affect the performance of the device. They are the same product in all aspect, except sterilization method.

8. Performance Testing

Mechanical performance of additional components are the same with the legally marketed device (unmodified) CastleLoc-P Anterior Cervical Plate System

(K143271). Therefore, we substitute mechanical test data of additional components of CastleLoc-P Anterior Cervical Plate System with the one of unmodified device (K143271).

The CastleLoc-P Anterior Cervical Plate System was tested according to ASTM F1717, specifically, Static compression test, Static torsion test, Static tension test and fatigue test.

9. Conclusion

The additional components of CastleLoc-P Anterior Cervical Plate System are as safe, as effective and perform as well as the predicate device. Therefore, the additional components of CastleLoc-P Anterior Cervical Plate System are substantially equivalent to the predicate device (K143271).