November 15, 2018

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: K183117
Trade/Device Name: PathLoc-L MIS Spinal System
Regulation Number: 21 CFR 888.3070
Regulation Name: Thoracolumbosacral pedicle screw system
Regulatory Class: Class II
Product Code: NKB
Dated: November 8, 2018
Received: November 9, 2018

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,

Colin O'neill -S for MNM

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)*
K183117

Device Name
PathLoc-L MIS Spinal System

Indications for Use *(Describe)*
The PathLoc-L MIS Spinal System is intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of acute and chronic instabilities or deformities of the thoracic, lumbar and sacral spine. The PathLoc-L MIS Spinal System can be used in an open approach and a percutaneous approach.

The PathLoc-L MIS Spinal System is intended for the following indications:

- Degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies)
- Spondylolisthesis
- Trauma (i.e., fracture or dislocation)
- Spinal stenosis
- Curvatures (i.e., scoliosis, kyphosis, lordosis)
- Tumor
- Pseudarthrosis
- Failed previous fusion

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.
   #201, #202 16-25, Dongbaekjungang-ro 16 beon-gil
   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 November 8th, 2018

2. **Device Identification**

Trade Name	PathLoc-L MIS Spinal System
Regulatory Class	Class II
Regulation Name/Common Name	Pedicle Screw Spinal System
Classification Name	Thoracolumbosacral pedicle screw system (21 CFR 888.3070)
Panel	Orthopedic
Product Code	NKB

3. **Purpose of 510(k)**
   L&K BIOMED Co. Ltd., is submitting this Special 510(k) to add new components and to change part number of two set screws of the existing 510(k)-cleared device (K161766)

4. **The name of the legally marketed (unmodified) device**
   ■ K161766 PathLoc-L MIS Spinal System (primary predicate)

5. **Description of the Device**
   PathLoc-L MIS Spinal System consists of poly screws, straight rods, curved rods and set screw components that can be used via percutaneous surgical approach. The components are available in a variety of diameters and lengths in order to accommodate patient anatomy and are made of titanium alloy (ASTM F136).

6. Indication for Use

The PathLoc-L MIS Spinal System is intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of acute and chronic instabilities or deformities of the thoracic, lumbar and sacral spine. The PathLoc-L MIS Spinal System can be used in an open approach and a percutaneous approach.

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- Degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies)
- Spondylolisthesis
- Trauma (i.e., fracture or dislocation)
- Spinal stenosis
- Curvatures (i.e., scoliosis, kyphosis, lordosis)
- Tumor
- Pseudarthrosis
- Failed previous fusion

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

The new components of the PathLoc-L MIS Spinal System are considered substantially equivalent to the referenced device (K161766). 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) and changed catalog number of two set screws of the existing device.

8. Performance Testing

Mechanical performance of additional components are the same with the legally marketed device (unmodified) PathLoc-L MIS Spinal System (K161766). Therefore, we substitute mechanical test data of additional components of PathLoc-L MIS Spinal System with the one of unmodified device (K161766).

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

The PathLoc-L MIS Spinal System was tested according to ASTM F1717, specifically, static compression test, static tension test, static torsion test and dynamic fatigue test, and under ASTM F543, axial pullout test.

9. Conclusion

The additional components of PathLoc-L MIS Spinal System are as safe, as effective and perform as well as the predicate device. Therefore, the additional components of PathLoc-L MIS Spinal System are substantially equivalent to the predicate device (K161766).