



August 22, 2016

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

L&K BIOMED Company, Limited
Ms. Yerim An
Regulatory Affairs Specialist
#201, 202 16-25, Dongbaekjungang-ro 16 Beon-gil
Giheung-gu, Yongin-si, Gyeonggi-do 446-916
KOREA

Re: K161766
Trade/Device Name: Pathloc-L MIS Spinal System
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle screw spinal system
Regulatory Class: Class III
Product Code: NKB, MNH, MNI
Dated: June 20, 2016
Received: June 27, 2016

Dear Ms. An:

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. 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 Parts 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely,

Vincent J. Devlin -S

for
Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K161766

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 Company, Limited
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 Giheung-gu, Yongin-si, Gyeonggi-do, 446-916, Korea
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Contact Person: Yerim An
Date prepared Aug, 12, 2016

2. **Device Identification**

Trade Name	PathLoc-L MIS Spinal System
Regulatory Class	Class III
Regulation Name/Common Name	Pedicle Screw Spinal System
Panel	Orthopaedic
Product Codes	NKB, MNH, MNI

3. **Purpose of 510(k)**

L&K BIOMED Co. Ltd., hereby submits this 510(k) proposing the addition of new screw types to the PathLoc-L MIS Spinal System.

4. **Predicate Device**

- Primary Predicate Device: K120140 LnK MIS Spinal System

5. **Description of the Device**

PathLoc-L MIS System consists of cannulated 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 from titanium alloy (ASTM F136). The implants will be provided non-sterile.

6. **Indication for Use**

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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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- 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 PathLoc-L MIS Spinal System is considered substantially equivalent to the legally marketed LnK MIS Spinal System (K120140). The systems have similar design, material, scientific technology, and indications for use. The only difference is the addition of different screw types which have been evaluated via mechanical testing.

8. Performance Testing

Pullout testing per ASTM F543-13 was performed on the subject screws and compared to a legally marketed predicate device. Results of the testing demonstrate substantially equivalent performance.

9. Conclusion

The PathLoc-L MIS Spinal System is substantially equivalent to a legally marketed predicate.