December 4, 2020

L&K BIOMED Co., Ltd.
Minju Choi
Official Correspondent
#201, #202 16-25, Dongbaekjungang-ro 16 beon-gil
Giheung-gu
Yongin-si, Gyeonggi-do 17015
Republic of Korea

Re: K200789
Trade/Device Name: LnK MIS Spinal System, PathLoc-L MIS Spinal System, AccelFix-MIS Spinal System
Regulation Number: 21 CFR 888.3070
Regulation Name: Thoracolumbosacral Pedicle Screw System
Regulatory Class: Class II
Product Code: NKB
Dated: November 6, 2020
Received: November 9, 2020

Dear Minju Choi:

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, 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)*
K200789

Device Name
LnK MIS Spinal System
PathLoc-L MIS Spinal System

Indications for Use *(Describe)*
The MIS Spinal Systems are 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 MIS Spinal System can be used in an open approach and a percutaneous approach.
The 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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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)*
K200789

Device Name
AccelFix-MIS Spinal System

Indications for Use *(Describe)*
The MIS Spinal Systems are 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 MIS Spinal System can be used in an open approach and a percutaneous approach.
The 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)

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L&K BIOMED

510(k) SUMMARY

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

1. Manufacturer

Submitter:	L&K BIOMED Co., Ltd.
	#201, #202 16-25, Dongbaekjungang-ro 16 beon-gil Giheung-gu, Yongin-si, Gyeonggi-do, 17015, Korea
	Phone: 82-10-5477-0325
Contact Person:	Min Ju Choi e-mail: jung9844@lnkbiomed.com

2. Device Identification

Trade Name	LnK MIS Spinal System PathLoc-L MIS Spinal System AccelFix-MIS Spinal System
Common Name	Pedicle Screw Spinal System
Class	Class II
Product Code	NKB
Classification Name	Thoracolumbosacral pedicle screw system
Regulation No.	(21 CFR 888.3070)
Panel	Orthopedic

3. Predicate or legally marketed devices which are substantially equivalent.

The additional models of the LnK MIS Spinal System, PathLoc-L MIS Spinal System and AccelFix-MIS Spinal System are considered substantially equivalent to the predicate devices. The systems have same design, scientific technology, and indications for use.

Primary Predicate:
AccelFix-MIS Spinal System (K182544)
Additional predicates:
LnK MIS Spinal System and PathLoc-L MIS Spinal System
(K112643, K120140, K161766, K183117)

4. Description of the Device

The MIS spinal 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 fabricated from titanium alloy (ASTM F136) and CoCrMo alloy (Cobalt-28Chromium-6Molybdenum, per ASTM F1537).

5. Indication for Use

The 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 MIS Spinal System can be used in an open approach and a percutaneous approach. The 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.

6. Performance Testing

The additional components to be added through this submission do not require additional mechanical testing. None of the additional components is the worst case of the LnK MIS Spinal System, PathLoc-L MIS Spinal System and AccelFix-MIS Spinal System. Therefore, we substitute mechanical test data of additional components of LnK MIS Spinal System, PathLoc-L MIS Spinal System and AccelFix-MIS Spinal System with the predicate device (K112643, K120140, K161766, K183117, K 182544).

7. Summary of Technology Characteristics

LnK MIS Spinal System, PathLoc-L MIS Spinal System and AccelFix-MIS Spinal System are substantially equivalent to the predicate devices in terms of design, scientific technology, same manufacturing process and indications for use.

8. Substantial Equivalence

LnK MIS Spinal System, PathLoc-L MIS Spinal System and AccelFix-MIS Spinal Fixation System were shown to be substantially equivalent to the predicate devices in indications for use, design, same manufacturing process and function.

9. Conclusion

The additional components perform as well as the predicate device. Therefore, the additional components of AccelFix MIS Spinal System, LnK MIS Spinal System and PathLoc-L MIS Spinal System are substantially equivalent to the predicate device (K112643, K120140, K161766, K183117, K182544).