DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

July 13, 2017

L&K BIOMED Co., Ltd.
Ms. Yerim An
RA Manager
#201, 202 16-25, Dongbaekjungang-ro 16 beon-gil
Giheung-gu, Yongin-si, Gyeonggi-do, 17015
KOREA

Re: K171813
Trade/Device Name: OpenLoc-L Spinal Fixation System, LnK Spinal Fixation System
Regulation Number: 21 CFR 888.3070
Regulation Name: Thoracolumbosacral pedicle screw system
Regulatory Class: Class II
Product Code: NKB, KWP, KWQ
Dated: June 16, 2017
Received: June 19, 2017

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 Part 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,

Mark N. Melkerson -S

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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K171813

Device Name
OpenLoc-L Spinal Fixation System, LnK Spinal Fixation System

Indications for Use *(Describe)*

Indications for Use (Describe)

OpenLoc-L Spinal Fixation System is non-cervical spinal fixation devices intended for use as posterior pedicle screw fixation system (T1-S2/ilium), or as an anterolateral fixation system (T8-L5). All components in the system are limited to skeletally mature patients. These devices are indicated as an adjunct to fusion for all of the following indications regardless of the intended use: degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies); spondylolisthesis; trauma (i.e., fracture or dislocation); deformities or curvatures (i.e., scoliosis, kyphosis, and/or lordosis); tumor; stenosis; and failed previous fusion (pseudoarthrosis).

The OpenLoc-L Spinal Fixation System is a pedicle screw system indicated for the treatment of severe spondylolisthesis (Grades 3 and 4) of the L5-S1 vertebra in skeletally mature patients receiving fusion by autogenous bone graft having implants attached to the lumbar and sacral spine (L3 to sacrum) with removal of the implants after the attainment of a solid fusion.

In addition, the OpenLoc-L Spinal Fixation System is intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar and sacral spine: degenerative spondylolisthesis with objective evidence of neurological impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (pseudoarthrosis).

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

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. 82-2-6717-1985
e-mail: yerim2706@lnkbiomed.com

Contact Person: Yerim An

Date prepared: July, 12, 2017

2. Device Identification

Trade Name	OpenLoc-L Spinal Fixation System LnK Spinal Fixation System
Common Name	Spinal Fixation Appliances
Product Code	NKB, KWP, KWQ
Regulatory Class	Class II
Classification Name	Thoracolumbosacral Pedicle Screw System, 21 CFR §888.3070 Spinal Interlaminal Fixation Orthosis, 21 CFR §888.3050 Spinal Intervertebral Body Fixation Orthosis, 21 CFR §888.3060

3. Purpose of 510(k)

The L&K BIOMED Co. Ltd., here by submits this special 510(k): device modification to request a modification for our previous LnK Spinal Fixation System. The modifications are to add new components and new brand name. We believe these modifications are eligible for the Special 510(k) process since they have the same fundamental scientific technology and intended use as the predicate device.

4. Predicate or legally marketed devices which are substantially equivalent

- LnK Spinal Fixation System K143363

5. Description of the Device

This system is comprised of screws, set screws, rods, crosslink, Hook and connectors. The components of this system are manufactured by Titanium

alloy (Titanium-6Aluminum-4Vanadium ELI, per ASTM F136) and CoCrMo alloy (Cobalt-28Chromium-6Molybdenum, per ASTM F1537). The screws are available from 4.0 to 8.5mm diameters with lengths ranging from 20-150mm.

Materials:

Product	Material	Standard
Screw	Ti-6Al-4V ELI	ASTM F136
Rod	Ti-6Al-4V ELI	ASTM F136
	Cobalt-28Chromium-6Molybdenum-4Vanadium ELI	ASTM F1537
Hook	Ti-6Al-4V ELI	ASTM F136
Set Screw	Ti-6Al-4V ELI	ASTM F136
Accessories	Ti-6Al-4V ELI	ASTM F136

Any implant components other than the rods are not manufactured from cobalt chrome.

6. Indication for Use

OpenLoc-L Spinal Fixation System is non-cervical spinal fixation devices intended for use as posterior pedicle screw fixation systems (T1-S2/ilium), or as an anterolateral fixation system (T8-L5). All components in the system are limited to skeletally mature patients. These devices are indicated as an adjunct to fusion for all of the following indications regardless of the intended use:

- degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies);
- spondylolisthesis;
- trauma (i.e., fracture or dislocation);
- deformities or curvatures (i.e., scoliosis, kyphosis, and/or lordosis);
- tumor;
- stenosis, and
- failed previous fusion (pseudoarthrosis)

The OpenLoc-L Spinal Fixation System is a pedicle screw system indicated for the treatment of severe Spondylolisthesis (Grade 3 and 4) of the L5-S1 vertebra in skeletally mature patients receiving fusion by autogenous bone graft having implants attached to the lumbar and sacral spine (L3 to sacrum) with removal of the implants after the attainment of a solid fusion.

In addition, the OpenLoc-L Spinal Fixation System is intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar and sacral spine: degenerative Spondylolisthesis with objective evidence of neurological impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor and failed previous fusion (pseudoarthrosis).

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

Applicant	L&K BIOMED Co.,Ltd.	L&K BIOMED Co.,Ltd.
Device Name	OpenLoc-L Spinal Fixation System LnK Spinal Fixation System	LnK Spinal Fixation System
	Subject Device	Predicate Device
510K No.		K143363
Regulation No.	888.3050, 888.3070	888.3050, 888.3070
Product Code	KWQ,KWP,NKB	MNI,MNH,KWQ,KWP,NKB
Class	Class II	Class II
Material	Titanium alloy (ASTM F136) CoCr Alloy (ASTM F1537)	Titanium alloy (ASTM F136) CoCr Alloy (ASTM F1537)
Sterile	Non-sterile	Non-sterile
Rod	Dia: 5.0/5.5/6.0mm Length:40~600mm	Dia: 5.0/5.5/6.0mm Length:40~600mm
Screw	Dia:4.0~8.5mm Length:20-150mm	Dia:4.0~8.5mm Length:20-150mm
Hooks	Ramped Hook - 6.0 Rod(Narrow, Standard, Wide) General Hook - 6.0 Rod(Narrow, Standard, Wide) Pedicle Hook - 6.0 Rod(Narrow, Standard, Wide) Angled Hook - 6.0 Rod(Right, Left) Offset Hook - 6.0 Rod(Right, Left)	Ramped Hook - 6.0 Rod(Narrow, Standard, Wide) General Hook - 6.0 Rod(Narrow, Standard, Wide) Pedicle Hook - 6.0 Rod(Narrow, Standard, Wide) Angled Hook - 6.0 Rod(Right, Left) Offset Hook - 6.0 Rod(Right, Left)
Indication for use	OpenLoc-L Spinal Fixation System is non-cervical spinal fixation devices intended for use as posterior pedicle screw fixation systems (T1-S2/ilium), or as an anterolateral fixation system (T8-L5). All components in the system are limited to skeletally mature patients. These devices are indicated as an adjunct to fusion for all of the following indications regardless of the intended use: *degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies); *spondylolisthesis; *trauma (i.e., fracture or dislocation); *deformities or curvatures (i.e., scoliosis, *kyphosis, and/or lordosis); *tumor; *stenosis, and *failed previous fusion (pseudoarthrosis) The OpenLoc-L Spinal Fixation System is a pedicle screw system indicated for the treatment of severe	LnK Spinal Fixation System is non-cervical spinal fixation devices intended for use as posterior pedicle screw fixation systems (T1-S2/ilium), or as an anterolateral fixation system (T8-L5). All components in the system are limited to skeletally mature patients. These devices are indicated as an adjunct to fusion for all of the following indications regardless of the intended use: *degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies); *spondylolisthesis; *trauma (i.e., fracture or dislocation); *deformities or curvatures (i.e., scoliosis, kyphosis, and/or lordosis); *tumor; *stenosis, and *failed previous fusion (pseudoarthrosis) The LnK Spinal Fixation System is a pedicle screw system indicated for the treatment of severe Spondylolisthesis (Grade 3 and 4) of the L5-S1 vertebra in skeletally mature patients receiving fusion

	Spondylolisthesis (Grade 3 and 4) of the L5-S1 vertebra in skeletally mature patients receiving fusion by autogenous bone graft having implants attached to the lumbar and sacral spine (L3 to sacrum) with removal of the implants after the attainment of a solid fusion. In addition, the OpenLoc-L Spinal Fixation System is intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar and sacral spine: degenerative Spondylolisthesis with objective evidence of neurological impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor and failed previous fusion (pseudoarthrosis).	by autogenous bone graft having implants attached to the lumbar and sacral spine (L3 to sacrum) with removal of the implants after the attainment of a solid fusion. In addition, the LnK Spinal Fixation System is intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar and sacral spine: degenerative Spondylolisthesis with objective evidence of neurological impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor and failed previous fusion (pseudarthrosis).

The OpenLoc-L Spinal Fixation System shares technological characteristics similar to the predicate device. These characteristics include similar design, the same materials, substantially equivalent performance characteristics and the same intended use.

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 OpenLoc-L Spinal Fixation System is substantially equivalent to the device referenced above.