



December 11, 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: K183168

Trade/Device Name: OpenLoc-L 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: November 15, 2018
Received: November 16, 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,


Ronald P. Jean -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)

K183168

Device Name

OpenLoc-L Spinal Fixation System

Indications for Use (Describe)

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 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 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.

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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 15th, 2018

2. **Device Identification**

Trade Name	OpenLoc-L 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

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

The L&K BIOMED Co. Ltd., hereby submits this Special 510(k): device modification to request a modification to our previous OpenLoc-L Spinal Fixation System. The modifications are to add new component, to change some of the part numbers, to change some of the anodizing colors of screws and to change size of crosslinks. 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**

- OpenLoc-L Spinal Fixation System K171813

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 using 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 10.0mm diameters with lengths from 20 to 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

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 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 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	OpenLoc-L Spinal Fixation System
	Subject Device	Predicate Device
510K No.		K171813
Regulation No.	888.3070	888.3070
Product Code	NKB, KWP, KWQ	NKB, KWP, KWQ
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:4.0~10.0mm 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) Pedicule 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) Pedicule Hook - 6.0 Rod(Narrow, Standard, Wide) Angled Hook - 6.0 Rod(Right, Left) Offset Hook - 6.0 Rod(Right, Left)
Indication for use	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);	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;

	• tumor; • stenosis, and • failed previous fusion (pseudoarthrosis) The 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 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).	● 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).
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8. Performance Testing

The additional size and components to be added through this submission do not require additional mechanical testing. None of the additional components is the worst case of the OpenLoc-L Spinal Fixation System as described in the worst case justification reports. Therefore, we substitute mechanical test data of additional components of OpenLoc-L Spinal Fixation System with the one of the unmodified device (K171813).

9. Conclusion

The OpenLoc-L Spinal Fixation System is substantially equivalent to the device referenced above and is therefore as safe and effective as the predicate devices for its intended use.