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

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).

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

   **Contact Person:** Yerim An

   **Date prepared:** July, 12, 2017

2. **Device Identification**

   **Trade Name**
   
   OpenLoc-L Spinal Fixation System

   **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., 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:

<table>
<thead>
<tr>
<th>Product</th>
<th>Material</th>
<th>Standard</th>
</tr>
</thead>
<tbody>
<tr>
<td>Screw</td>
<td>Ti-6Al-4V ELI</td>
<td>ASTM F136</td>
</tr>
<tr>
<td>Rod</td>
<td>Ti-6Al-4V ELI</td>
<td>ASTM F136</td>
</tr>
<tr>
<td></td>
<td>Cobalt-28Chromium-6Molybdenum-4Vanadium ELI</td>
<td>ASTM F1537</td>
</tr>
<tr>
<td>Hook</td>
<td>Ti-6Al-4V ELI</td>
<td>ASTM F136</td>
</tr>
<tr>
<td>Set Screw</td>
<td>Ti-6Al-4V ELI</td>
<td>ASTM F136</td>
</tr>
<tr>
<td>Accessories</td>
<td>Ti-6Al-4V ELI</td>
<td>ASTM F136</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Applicant</th>
<th>L&amp;K BIOMED Co.,Ltd.</th>
<th>L&amp;K BIOMED Co.,Ltd.</th>
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</thead>
<tbody>
<tr>
<td>Device Name</td>
<td>OpenLoc-L Spinal Fixation System</td>
<td>LnK Spinal Fixation System</td>
</tr>
<tr>
<td>510K No.</td>
<td></td>
<td>K143363</td>
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<td>888.3050, 888.3070</td>
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<td>Product Code</td>
<td>KWQ, KWP, NKB</td>
<td>MNI, MNH, KWQ, KWP, NKB</td>
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<tr>
<td>Class</td>
<td>Class II</td>
<td>Class II</td>
</tr>
<tr>
<td>Sterile</td>
<td>Non-sterile</td>
<td>Non-sterile</td>
</tr>
<tr>
<td>Rod</td>
<td>Dia: 5.0/5.5/6.0mm Length: 40~600mm</td>
<td>Dia: 5.0/5.5/6.0mm Length: 40~600mm</td>
</tr>
<tr>
<td>Screw</td>
<td>Dia: 4.0<del>8.5mm Length: 20</del>150mm</td>
<td>Dia: 4.0<del>8.5mm Length: 20</del>150mm</td>
</tr>
</tbody>
</table>

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)

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:

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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.

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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 (pseudoarthrosis).

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.