DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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November 3, 2016

L&K BIOMED Co., Ltd.
% Ms. Yerim An
RA Specialist
L&K Biomed Co., Ltd.
#201, 202 16-25, Dongbaekjungang-ro 16 Beon-gil
Giheung-gu, Yongin-si, 446-916
KOREA

Re: K162136
Trade/Device Name: LnK Posterior Cervical Fixation System/CastleLoc-S Posterior Cervical Fixation System
Regulatory Class: Unclassified
Product Code: NKG, KWP, MNI
Dated: October 5, 2016
Received: October 7, 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" (21CFR 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

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)*
K162136

Device Name
CastleLoc-S Posterior Cervical Fixation System
LnK Posterior Cervical Fixation System

Indications for Use *(Describe)*

CastleLoc-S Posterior Cervical Fixation System:

The CastleLoc-S Posterior Cervical Fixation System is intended to provide immobilization and stabilization of spinal segments as an adjunct to fusion for the following acute and chronic instabilities of the cervical spine (C1 to C7) and the thoracic spine (T1-T3): traumatic spinal fractures and/or traumatic dislocations; instability or deformity; failed previous fusions (e.g., pseudoarthrosis); tumors involving the cervical spine; and degenerative disease, including intractable radiculopathy and/or myelopathy, neck and/or arm pain of discogenic origin as confirmed by radiographic studies, and degenerative disease of the facets with instability. The CasteLoc-S Posterior Cervical Fixation System is also intended to restore the integrity of the spinal column even in the absence of fusion for a limited time period in patients with advanced stage tumors involving the cervical spine in whom life expectancy is of insufficient duration to permit achievement of fusion.

The CastleLoc-S Posterior Cervical Fixation System can be linked to the LnK Spinal Fixation System and PathLoc-C Posterior Cervical Fixation System via rod to rod connector and transitional rod.

LnK Posterior Cervical Fixation System:

The LnK Posterior Cervical Fixation System is intended to provide immobilization and stabilization of spinal segments as an adjunct to fusion for the following acute and chronic instabilities of the cervical spine (C1 to C7) and the thoracic spine (T1-T3): traumatic spinal fractures and/or traumatic dislocations; instability or deformity; failed previous fusions (e.g., pseudoarthrosis); tumors involving the cervical spine; and degenerative disease, including intractable radiculopathy and/or myelopathy, neck and/or arm pain of discogenic origin as confirmed by radiographic studies, and degenerative disease of the facets with instability. The LnK Posterior Cervical Fixation System is also intended to
restore the integrity of the spinal column even in the absence of fusion for a limited time period in patients with advanced stage tumors involving the cervical spine in whom life expectancy is of insufficient duration to permit achievement of fusion

The LnK Posterior Cervical Fixation System can be linked to the LnK Spinal Fixation System and PathLoc-C Posterior Cervical Fixation System via rod to rod connector and transitional rod.

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, 446-916, Korea
Phone. 82-2-6717-1985
e-mail: yerim2706@gmail.com

**Contact Person:** Yerim An

**Date prepared:** Nov. 1, 2016

**2. Device Identification**

| | |
|---|---|
| Trade Name | CastleLoc-S Posterior Cervical Fixation System; LnK Posterior Cervical Fixation System |
| Common Name | Spinal Fixation System |
| Product Code | NKG, KWP |
| Regulatory Class | Unclassified |
| Classification Name | Unclassified |

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

The L&K BIOMED Co.Ltd, here by submits this traditional 510(k): to request posterior cervical screw indications and to include new accessories and additional sizes of rods and partially screws in our previous LnK Posterior Cervical Fixation System and introduce CastleLoc-S Posterior Cervical Fixation System.

**4. Predicate or legally marketed devices which are substantially equivalent**

**Primary Predicate: OASYS® System (K151755)**

**Additional Device: LnK Posterior Cervical Fixation System (K143278)**

## 5. Description of the Device

The CastleLoc-S Posterior Cervical Fixation System and LnK Posterior Cervical Fixation System are a top-loading, multiple component, posterior (cervical-thoracic) spinal fixation system which consists of polyscrew, Reduction poly screw, partially screw, semi-reduction partially screw, straight rod, curved rod, transitional rod, set screw, hooks and accessories that can be used via an open surgical approach.

**Materials:**

| Product | Material | Standard |
|---|---|---|
| Cervical 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

For CastleLoc-S Posterior Cervical Fixation System

The CastleLoc-S Posterior Cervical Fixation System is intended to provide immobilization and stabilization of spinal segments as an adjunct to fusion for the following acute and chronic instabilities of the cervical spine (C1 to C7) and the thoracic spine from T1-T3: traumatic spinal fractures and/or traumatic dislocations; instability or deformity; failed previous fusions (e.g., pseudarthrosis); tumors involving the cervical spine; and degenerative disease, including intractable radiculopathy and/or myelopathy, neck and/or arm pain of discogenic origin as confirmed by radiographic studies, and degenerative disease of the facets with instability. The CastleLoc-S Posterior Cervical Fixation System is also intended to restore the integrity of the spinal column even in the absence of fusion for a limited time period in patients with advanced stage tumors involving the cervical spine in whom life expectancy is of insufficient duration to permit achievement of fusion

The CastleLoc-S Posterior Cervical Fixation System can be linked to the LnK Spinal Fixation System and PathLoc-C Posterior Cervical Fixation System via rod to rod connector and transitional rod.

For LnK Posterior Cervical Fixation System

The LnK Posterior Cervical Fixation System is intended to provide immobilization and stabilization of spinal segments as an adjunct to fusion for the following acute and chronic instabilities of the cervical spine (C1 to C7) and the thoracic spine from T1-T3: traumatic spinal fractures and/or traumatic dislocations; instability or deformity; failed previous fusions (e.g., pseudarthrosis); tumors involving the cervical spine; and degenerative disease, including intractable radiculopathy and/or myelopathy, neck and/or arm pain of discogenic origin as confirmed by radiographic studies, and degenerative disease of the facets with instability. The LnK Posterior Cervical Fixation System is also intended to restore the integrity of the spinal column even in the absence of fusion for a limited time period in patients with advanced stage tumors involving the cervical spine in whom life expectancy is of insufficient duration to permit achievement of fusion
The LnK Posterior Cervical Fixation System can be linked to the LnK Spinal Fixation System and PathLoc-C Posterior Cervical Fixation System via rod to rod connector and transitional rod.

## 7. Comparison of the technological characteristics of the subject and predicate devices

For CastleLoc-S Posterior Cervical Fixation System

The CastleLoc-S Posterior Cervical Fixation System is considered substantially equivalent to legally marketed devices OASYS system. They are similar in design, material, scientific technologies and indications for use.

| **Applicant** | **L&K BIOMED Co.,Ltd.** | **Stryker** |
|---|---|---|
| **Device Name** | **CastleLoc-S Posterior Cervical Fixation System** | **OASYS System** |
| | Subject Device | Primary Predicate Device |
| **510K No.** | K162136 | K151755 |
| **Regulation No.** | 888.3050 | 888.3050 |
| **Product Code** | NKG, KWP | NKG, KWP |
| **Class** | Unclassified | Unclassified |
| **Material** | Titanium alloy (ASTM F136)<br>CoCr Alloy (ASTM F1537) | Titanium alloy, CP Titanium, Vitallium |
| **Sterile** | Non-sterile | Non-sterile |
| **Indication for use** | The CastleLoc-S Posterior Cervical Fixation System is intended to provide immobilization and stabilization of spinal segments as an adjunct to fusion for the following acute and chronic instabilities of the cervical spine (C1 to C7) and the thoracic spine from T1-T3: | The Stryker Spine OASYS® System is intended to provide immobilization and stabilization of spinal segments as an adjunct to fusion for the following acute and chronic instabilities of the craniocervical junction, the cervical spine (C1 to C7) and the thoracic |

| | | |
|---|---|---|
| | traumatic spinal fractures and/or traumatic dislocations; instability or deformity; failed previous fusions (e.g., pseudarthrosis); tumors involving the cervical spine; and degenerative disease, including intractable radiculopathy and/or myelopathy, neck and/or arm pain of discogenic origin as confirmed by radiographic studies, and degenerative disease of the facets with instability. The CastleLoc-S Posterior Cervical Fixation System is also intended to restore the integrity of the spinal column even in the absence of fusion for a limited time period in patients with advanced stage tumors involving the cervical spine in whom life expectancy is of insufficient duration to permit achievement of fusion<br>The CastleLoc-S Posterior Cervical Fixation System can be linked to the LnK Spinal Fixation System and PathLoc-C Posterior Cervical Fixation System via rod to rod connector and transitional rod. | spine (T1-T3): traumatic<br>spinal fractures and/or traumatic dislocations; instability or deformity;<br>failed previous fusions (e.g. pseudoarthrosis); tumors involving the<br>cervical/thoracic spine; and degenerative disease, including<br>intractable radiculopathy and/or myelopathy, neck and/or arm pain<br>of discogenic origin as confirmed by radiographic studies, and<br>degenerative disease of the facets with instability.<br>The Stryker Spine OASYS® System is also intended to restore the<br>integrity of the spinal column even in the absence of fusion for a<br>limited time period in patients with advanced stage tumors involving<br>the cervical spine in whom life expectancy is of insufficient duration to<br>permit achievement of fusion.<br>The Stryker Spine OASYS® System can be linked to the Xia® System,<br>SR90D System and Xia® 4.5 Spinal System via the rod-to-rod<br>connectors and transition rods.<br>The Stryker Spine OASYS® System can also be linked to the polyaxial<br>screws of the Xia® II and Xia® 3 Systems via the saddle connector. |

For LnK Posterior Cervical Fixation System

The LnK Posterior Cervical Fixation System is considered substantially equivalent to legally marketed devices OASYS system. They are similar in design, material, scientific technologies and indications for use.

| **Applicant** | **L&K BIOMED Co.,Ltd.** | **Stryker** |
|---|---|---|
| **Device Name** | **LnK Posterior Cervical Fixation System** | **OASYS System** |
| | Subject Device | Primary Predicate Device |
| **510K No.** | K162136 | K151755 |
| **Regulation No.** | 888.3050 | 888.3050 |
| **Product Code** | NKG, KWP | NKG, KWP |
| **Class** | Unclassified | Unclassified |
| **Material** | Titanium alloy (ASTM F136)<br>CoCr Alloy (ASTM F1537) | Titanium alloy, CP Titanium, Vitallium |
| **Sterile** | Non-sterile | Non-sterile |
| **Indication for use** | The LnK Posterior Cervical Fixation System is intended to provide immobilization and stabilization of spinal segments as an adjunct to fusion for the following acute and chronic instabilities of the cervical spine (C1 to C7) and | The Stryker Spine OASYS® System is intended to provide immobilization<br>and stabilization of spinal segments as an adjunct to fusion for the<br>following acute and chronic instabilities of the |

| | | |
|---|---|---|
| | the thoracic spine from T1-T3: traumatic spinal fractures and/or traumatic dislocations; instability or deformity; failed previous fusions (e.g., pseudarthrosis); tumors involving the cervical spine; and degenerative disease, including intractable radiculopathy and/or myelopathy, neck and/or arm pain of discogenic origin as confirmed by radiographic studies, and degenerative disease of the facets with instability. The CastleLoc-S Posterior Cervical Fixation System is also intended to restore the integrity of the spinal column even in the absence of fusion for a limited time period in patients with advanced stage tumors involving the cervical spine in whom life expectancy is of insufficient duration to permit achievement of fusion<br>The LnK Posterior Cervical Fixation System can be linked to the LnK Spinal Fixation System and PathLoc-C Posterior Cervical Fixation System via rod to rod connector and transitional rod. | craniocervical junction,<br>the cervical spine (C1 to C7) and the thoracic spine (T1-T3): traumatic<br>spinal fractures and/or traumatic dislocations; instability or deformity;<br>failed previous fusions (e.g. pseudoarthrosis); tumors involving the<br>cervical/thoracic spine; and degenerative disease, including<br>intractable radiculopathy and/or myelopathy, neck and/or arm pain<br>of discogenic origin as confirmed by radiographic studies, and<br>degenerative disease of the facets with instability.<br>The Stryker Spine OASYS® System is also intended to restore the<br>integrity of the spinal column even in the absence of fusion for a<br>limited time period in patients with advanced stage tumors involving<br>the cervical spine in whom life expectancy is of insufficient duration to<br>permit achievement of fusion.<br>The Stryker Spine OASYS® System can be linked to the Xia® System,<br>SR90D System and Xia® 4.5 Spinal System via the rod-to-rod<br>connectors and transition rods.<br>The Stryker Spine OASYS® System can also be linked to the polyaxial<br>screws of the Xia® II and Xia® 3 Systems via the saddle connector. |

## 8. Performance Testing

(1) ASTM F 1717

- Static and Dynamic Compression Bending
- Static Torsion
- Static Tension

(2) ASTM F 1798

- Axial Gripping Capacity
- Torsional Gripping Capacity
- Transverse Moment

## 9. Conclusion

The CastleLoc-S Posterior Cervical Fixation System and LnK Posterior Cervical Fixation System are substantially equivalent to legally marketed predicates.