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

L&K Biomed Company, Limited
Ms. Yerim An
Regulatory Affairs Specialist
#201, 202 16-25, Dongbaekjungang-ro 16 Beon-gil
Giheung-gu, Yongin-si, Gyeonggi – do 446-916
KOREA

July 21, 2016

Re: K153439
Trade/Device Name: PathLoc-C Posterior Cervical Fixation System
Regulation Number: Unclassified
Product Code: NKG
Dated: May 25, 2015
Received: May 31, 2015

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 yours,

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)*
K153439

Device Name
PathLoc-C Posterior Cervical Fixation System

Indications for Use *(Describe)*
The PathLoc-C 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 PathLoc-C 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.

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 May 25, 2015

2. **Device Identification**

Trade Name	PathLoc-C Posterior Cervical Fixation System
Classification	Unclassified Posterior, Cervical Pedicle Screw Spine Fixation Orthopaedic and Rehabilitation Devices Panel Unclassified; Pre-Amendment Device Product Code: NKG

3. **Purpose of 510(k)**
The L&K BIOMED Co., Ltd, here by submits this traditional 510(k): PathLoc-C Posterior Cervical Fixation System.

4. **Predicate and Reference Devices:**
- **Primary Predicate Device: VERTEX® Reconstruction System** (K143471)
- **Additional Predicate Device: OASYS® System** (K151755)
- **Reference Device: LnK Posterior Cervical Fixation System**(K143278)

5. **Description of the Device**

The PathLoc-C Posterior Cervical Fixation System is a top-loading, multiple component, posterior (cervical-thoracic) spinal fixation system which consists of polyscrews, straight rods, curved rods and set screw 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
Set Screw	Ti-6Al-4V ELI	ASTM F136

6. Indication for Use

The PathLoc-C 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 PathLoc-C 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.

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

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

8. Performance Testing

Mechanical testing performed with the PathLoc-C Posterior Cervical Fixation System demonstrated equivalence of the device to legally marketed predicate devices. Mechanical test reports were completed for the following test methods:

(1) Static compression bending testing was performed per ASTM F1717.

(2) Static tension testing was performed per ASTM F1717.

(3) Static torsion testing was performed per ASTM F1717.

(4) Dynamic compression bending testing was performed per ASTM F1717.

9. Conclusion

The PathLoc-C Posterior Cervical Fixation System is substantially equivalent to legally marketed predicates.