July 16, 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: K181600
Trade/Device Name: PathLoc-SI Joint Fusion System
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: OUR
Dated: June 15, 2018
Received: June 18, 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. 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.

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K181600

Device Name
PathLoc-SI Joint Fusion System

Indications for Use *(Describe)*
The PathLoc-SI Joint Fusion System is intended for sacroiliac joint fusion for conditions including sacroiliac joint disruptions and degenerative sacroiliitis.

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.
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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: June 15th, 2018

2. **Device Identification**

Trade Name	PathLoc-SI Joint Fusion System
Common Name	Sacroiliac Joint Fixation / Sacroiliac Joint Fusion
Product Code	OUR
Regulatory Class	II
Classification Name	21 CFR 888.3040 Smooth or threaded metallic bone fixation fastener

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

The L&K BIOMED Co. Ltd. hereby submits this special 510(k): to register additional size and additional components of the PathLoc-SI Joint Fusion System

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

- **Primary Predicate(unmodified device):** K153656 PathLoc-SI Joint Fusion System

5. **Description of the Device**

PathLoc-SI Joint Fusion System consists of different diameter bone screws in various lengths and thread configurations to accommodate variations in patient anatomy. The material is Titanium alloy (Titanium-6Aluminum-4Vanadium ELI, per ASTM F136) approved for medical use.

- Arch Screw will be implanted in patient's bone then autograft will be inserted.
- Locking Screw can be used with washer or can be used on its own
- Self-tapping flute centers screw for easy insertion

Materials:

Product	Material	Standard
Arch Screw	Ti-6Al-4V ELI	ASTM F136
Locking Screw	Ti-6Al-4V ELI	ASTM F136
Washer	Ti-6Al-4V ELI	ASTM F136

6. Indication for Use

The PathLoc-SI Joint Fusion System is intended for sacroiliac joint fusion for conditions including sacroiliac joint disruptions and degenerative sacroiliitis.

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

The PathLoc-SI Joint Fusion System is considered substantially equivalent to the unmodified device (PathLoc-SI Joint Fusion System, K153656). They are similar in design and have the same material, and the same indications for use.

	Subject Device	Predicate Device (unmodified)
Item	PathLoc-SI Joint Fusion System	PathLoc-SI Joint Fusion System
Manufacturer	L&K BIOMED Co.,Ltd.	L&K BIOMED Co.,Ltd.
Material	Ti-6Al-4V ELI	Ti-6Al-4V ELI
510(K) No		K153656
Product Code	OUR	OUR
Regulation No.	21CFR888.3040	21CFR888.3040
Class	ClassⅡ	ClassⅡ
Intended Use	The PathLoc-SI Joint Fusion System is intended for sacroiliac joint fusion for conditions including sacroiliac joint disruptions and degenerative sacroililtis.	The PathLoc-SI Joint Fusion System is intended for sacroiliac joint fusion for conditions including sacroiliac joint disruptions and degenerative sacroililtis.

8. Performance Testing

ASTM F543-13 Standard

- Torsional test
- Axial pullout test
- Driving torque test(Insertion/Removal)

ASTM F2193-14 Standard

- Static and fatigue bending strength of metallic spinal screw

9. Conclusion

The PathLoc-SI Joint Fusion System is substantially equivalent to the unmodified device (K153656)