February 23, 2024

L&K Biomed Co., Ltd.
Kihyang Kim
#101, 201, 202 16-25, Dongbaekjungang-ro 16 beon-gil
Giheung-gu
Yongin-si, Gyeonggi 17015
South Korea

Re: K240201
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: January 20, 2024
Received: January 25, 2024

Dear Kihyang Kim:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Colin O'neill -S

Colin O'Neill, M.B.E.
Assistant Director
DHT6B: Division of Spinal Devices
OHT6: Office of Orthopedic Devices
Office of Product Evaluation and Quality
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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K240201

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) SUMMARY

The following 510(k) summary is being submitted as required by 21 CFR 807.92(a):

1. MANUFACTURER

Submitter's Name:	L&K Biomed Co., Ltd.
Submitter's Address:	#101, 201, 202 16-25, Dongbaekjungang-ro 16 beon-gil Giheung-gu, Yongin-si, Gyeonggi-do, 17015, South Korea.
Submitter's Telephone:	82-2-6717-1983
Contact Person:	Kihyang Kim khkim@lnkbiomed.com
Prepared Date:	Jan 24, 2024

2. DEVICE IDENTIFICATION

Device Trade Name	PathLoc SI Joint Fusion System
Common/Usual Name	Sacroiliac Joint Fixation, Bone Screw
Regulation Class /Number	Class II / 21 CFR 888.3040
Regulation Name	Smooth or threaded metallic bone fixation fastener
Product Code	OUR
Classification Panel	Spinal Devices (DHT6B)

3. PREDICATE OR LEGALLY MARKETED DEVICES WHICH ARE SUBSTANTIALLY EQUIVALENT.

Subject Device Name	510K NO.	Trade or Proprietary or Model Name	Predicate Type
PathLoc SI Joint Fusion System	K231841	PathLoc SI Joint Fusion System	Primary

The design features, indications for use, material and manufacturing process for the subject devices are substantially equivalent to the predicate devices.

4. MATERIALS

PATHLOC SI Joint Fusion System	Ti-6Al-4V ELI titanium alloy (ASTM F136)

The additional components material is the same material used in the predicate devices (K231841).

5. DESCRIPTION OF THE DEVICE

The PATHLOC SI Joint Fusion System consists of different diameter bone screws in various lengths and thread configurations to accommodate variations in patient anatomy. The devices are manufactured from titanium alloy per ASTM F136. This submission adds an additional screw option to the system.

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. PERFORMANCE TESTING

PATHLOC SI Joint Fusion System

An engineering analysis was utilized to determine that the additional components do not introduce a new worst case for device performance. None of the additional components is the worst case of the PathLoc SI Joint Fusion System and the additional components to be added through this submission do not require additional mechanical testing.

8. SUMMARY OF TECHNOLOGY CHARACTERISTICS

Subject devices are identical to the predicate devices in material, Indication for use, manufacturing process, and surgical approach.

9. SUBSTANTIAL EQUIVALENCE

Subject devices are shown to be substantially equivalent to the predicate devices in indications for use, design, function and materials used.

10. CONCLUSION

The overall technology characteristics lead to the conclusion that the PathLoc SI Joint Fusion System is substantially equivalent to the predicate devices (K231841).