December 23, 2022

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

Re: K223565
Trade/Device Name: LnK Spinal Fixation System /OpenLoc-L Spinal Fixation System, AccelFix 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: November 26, 2022
Received: November 29, 2022

Dear Katherine 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 (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 located 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.

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) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; 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 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,

Anne D. Talley -S for

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K223565

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

Indications for Use *(Describe)*

The LnK Spinal Fixation System /OpenLoc-L Spinal Fixation System is a non-cervical spinal fixation device intended for use as a 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. This device is 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).

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.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K223565

Device Name
AccelFix Spinal Fixation System

Indications for Use *(Describe)*

The AccelFix Spinal Fixation System is a non-cervical spinal fixation device intended for use as a 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).

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. SUBMITTER

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, Korea
Submitter's Telephone:	+82-2-6717-1983
Contact Person:	Katherine Kim khkim@lnkbiomed.com / ra@lnkbiomed.com
Prepared Date	December 20, 2022

2. DEVICE IDENTIFICATION

Trade or Proprietary Name	LnK Spinal Fixation System /OpenLoc-L Spinal Fixation System
Common or Usual Name	Spinal interlaminal fixation orthosis Spinal intervertebral body fixation orthosis Thoracolumbosacral pedicle screw system
Regulation class / Number	Class II, 21 CFR 888.3070
Regulation Name	Thoracolumbosacral pedicle screw system
Product Code	NKB, KWP, KWQ
Classification Panel	Spinal Devices (DHT6B)

Trade or Proprietary Name	AccelFix Spinal Fixation System
Common or Usual Name	Spinal interlaminal fixation orthosis Spinal intervertebral body fixation orthosis Thoracolumbosacral pedicle screw system
Regulation class / Number	Class II, 21 CFR 888.3070
Regulation Name	Thoracolumbosacral pedicle screw system
Product Code	NKB, KWP, KWQ
Classification Panel	Spinal Devices (DHT6B)

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

The additional components of the LnK Spinal Fixation System, OpenLoc-L Spinal Fixation System 18and AccelFix Spinal Fixation System are considered substantially equivalent to the predicate devices. The systems have same design, materials, scientific technology, and indications for use.

LnK Spinal Fixation System /OpenLoc-L Spinal Fixation System

- Primary predicate: LnK Spinal Fixation System (K120270)
- Additional predicates: LnK Spinal Fixation System /OpenLoc-L Spinal Fixation System (K143363, K171813, K183168, K 200790)

AccelFix Spinal Fixation System

- Primary Predicate: AccelFix Spinal Fixation System (K182544)
- Additional predicate: AccelFix Spinal Fixation System (K200794)

4. MATERIALS

LnK Spinal Fixation System/ OpenLoc-L Spinal Fixation System AccelFix Spinal Fixation System	Ti-6Al-4V ELI titanium alloy (ASTM F136) and Cobalt-28Chromium-6Molybdenum-4Vanadium ELI (ASTM F1537)

And the additional domino connector w type is manufactured from Ti-6Al-4V ELI titanium alloy (ASTM F136). This this is the same material used in the predicate devices.

5. DESCRIPTION OF THE DEVICE

LNK SPINAL FIXATION SYSTEM /OPENLOC-L SPINAL FIXATION SYSTEM

The LNK SPINAL FIXATION SYSTEM, OPENLOC-L SPINAL FIXATION SYSTEM are available in various sizes. This system is comprised of screws, set screws, rods, crosslinks, connectors and hooks. The screws are available from 4.0 mm to 10.5 mm diameters with lengths ranging from 20 mm to 150 mm. The rods are available from 5.0 mm, 5.5 mm, 6.0 mm and 6.35 mm diameter with lengths ranging from 40 mm to 600 mm. Both straight rods and curved rods have four types of design that consist of standard type, hex type, stopper type and double stopper.

ACCELFIX SPINAL FIXATION SYSTEM

The AccelFix Spinal Fixation System consists of screws, rods, crosslinks, set screws, cross-link connectors, and hooks. The screws are available from 5.0 mm, 5.5 mm, 6.0 mm, 7.0, 7.5, 8.0, 8.5, 9.0 and 9.5mm diameters with lengths ranging from 30 mm to 150 mm. The rods are available from 5.5 mm, 6.0mm and 6.35mm diameter with lengths ranging from 40 mm to 600 mm. Both straight rods and curved rods have four types of design that consist of standard type, hex type, stopper type and double stopper.

6. INDICATION FOR USE

LNK SPINAL FIXATION SYSTEM /OPENLOC-L SPINAL FIXATION SYSTEM

The LnK Spinal Fixation System /OpenLoc-L Spinal Fixation System is a non-cervical spinal fixation device intended for use as a 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. This device is 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).

ACCELFIX SPINAL FIXATION SYSTEM

The AccelFix Spinal Fixation System is a non-cervical spinal fixation device intended for use as a 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).

7. PERFORMANCE DATA

The additional components to be added through this submission do not require additional mechanical testing. None of the additional components is the worst case of the LnK Spinal Fixation System, OpenLoc-L Spinal Fixation System and AccelFix Spinal Fixation System. Therefore, we substitute mechanical test data of additional components of LnK Spinal Fixation System, OpenLoc-L Spinal Fixation System and AccelFix Spinal Fixation System with the predicate device (LnK Spinal Fixation System, OpenLoc-L Spinal Fixation System -K120270, K143363, K171813, K183168, K200790, / AccelFix Spinal Fixation System: K182544, K200794).

8. SUMMARY OF TECHNICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The subject and predicate devices have nearly identical technological characteristics and the minor differences do not raise any new issues of safety and effectiveness. Specifically, the following characteristics are identical between the subject and predicates:

- Instruction for use
- Design
- Dimension
- Material
- Approach
- Sterilization & Method

The following technological similarities and differences exist between the subject and predicate devices:

LnK Spinal Fixation System, OpenLoc-L Spinal Fixation System

Characteristics		This subject	Predicate device
Instruction for use	Similarities	Instruction for use including indication for use are same	
Design	Similarities	This Domino Connector W Type (OpenLoc-L) belongs to Rod-to-Rod connector type, and this connector is used to connect rod to rod.	Predicate domino connector belongs to Rod-to-Rod connector type, and this connector is used to connect rod to rod.
	Differences	This Domino Connector W Type (OpenLoc-L), there are two open holes in the top, slide the rod from top to bottom into these open holes and tighten with set screws.	The predicate domino connector has two holes on the side where rods can be inserted and is connected by inserting rods into the two holes.
		The rod diameter that can be used for the added Domino connector W type (OpenLoc-L) is 5.5mm rod and 6mm rod.	The rod diameter that can be used for the Predicate domino connector is from 5.0mm rod to 6.35mm rod.
Material	Similarities	The raw materials of LnK Spinal Fixation System/OpenLoc-L Spinal Fixation System are made of Ti-6Al-4V ELI titanium alloy (ASTM F136) and Cobalt-28Chromium-6Molybdenum-4Vanadium ELI (ASTM F1537).	The raw materials of LnK Spinal Fixation System/OpenLoc-L Spinal Fixation System are made of Ti-6Al-4V ELI titanium alloy (ASTM F136) and Cobalt-28Chromium-6Molybdenum-4Vanadium ELI (ASTM F1537).
		This Domino Connector W Type (OpenLoc-L) is made of Ti-6Al-4V ELI titanium alloy (ASTM F136).	Predicate device (domino connector) is made of Ti-6Al-4V ELI titanium alloy (ASTM F136).
Approach	Similarities	Use a similar approach	
Sterilization & Method	Similarities	• Sterile device: Gamma radiation • Non-sterile device: recommended steam sterilization (autoclave sterilization)	• Sterile device: Gamma radiation • Non-sterile device: recommended steam sterilization (autoclave sterilization)
Manufacturing process Similarities		Manufacturing process of additional Domino Connector W Type (OpenLoc-L) and predicate domino connector are same.	

AccelFix Spinal Fixation System

Characteristics		This subject	Predicate device
Instruction for use	Similarities	Instruction for use including indication for use are same	
Design	Similarities	This Domino Connector W Type (AccelFix) belongs to Rod-to-Rod connector type, and this connector is used to connect rod to rod.	Predicate domino connector belongs to Rod-to-Rod connector type, and this connector is used to connect rod to rod.
	Differences	This Domino Connector W Type (AccelFix), there are two open holes in the top, slide the rod from top to bottom into these open holes and tighten with set screws.	The predicate domino connector has two holes on the side where rods can be inserted and is connected by inserting rods into the two holes.
		The rod diameter that can be used for the added Domino connector W type (AccelFix) is 5.5mm rod and 6mm rod.	The rod diameter that can be used for the Predicate domino connector is from 5.0mm rod to 6.35mm rod.
Material	Similarities	The raw materials of AccelFix Spinal Fixation System are made of Ti-6Al-4V ELI titanium alloy (ASTM F136) and Cobalt-28Chromium-6Molybdenum-4Vanadium ELI (ASTM F1537).	The raw materials of AccelFix Spinal Fixation System are made of Ti-6Al-4V ELI titanium alloy (ASTM F136) and Cobalt-28Chromium-6Molybdenum-4Vanadium ELI (ASTM F1537).
		This Domino Connector W Type (AccelFix) is made of Ti-6Al-4V ELI titanium alloy (ASTM F136).	Predicate device (domino connector) is made of Ti-6Al-4V ELI titanium alloy (ASTM F136)
Approach	Similarities	Use a similar approach	
Sterilization & Method	Similarities	• Sterile device: Gamma radiation • Non-sterile device: recommended steam sterilization (autoclave sterilization)	• Sterile device: Gamma radiation • Non-sterile device: recommended steam sterilization (autoclave sterilization)
Manufacturing process Similarities		Manufacturing process of additional Domino Connector W Type (AccelFix) and predicate domino connector are same.	

9. SUBSTANTIAL EQUIVALENCE AND CONCLUSION

The subject additional components of LnK Spinal Fixation System/ OpenLoc-L Spinal Fixation System and AccelFix Spinal Fixation System have been found to be substantially equivalent to the predicate devices with respect to technical characteristics, performance, and intended use.

The information provided within this premarket notification supports substantial equivalence of the subject device to the predicate devices. The overall data lead to the conclusion that the additional components of LnK Spinal Fixation System/ OpenLoc-L Spinal Fixation System and AccelFix Spinal Fixation System are substantially equivalent to the predicate devices (K120270, K143363, K171813, K183168, K200790, K182544, K200794).