August 24, 2023

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: K231680
Trade/Device Name: AccelFix Lumbar Expandable Cage System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: MAX
Dated: July 31, 2023
Received: August 2, 2023

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,

Brent Showalter -S

Brent Showalter, Ph.D.
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)*
K231680

Device Name
AccelFix Lumbar Expandable Cage System

Indications for Use *(Describe)*
AccelFix Lumbar Expandable Cage System is indicated for intervertebral body fusion procedures in skeletally mature patients with degenerative disc disease (DDD) at one or two contiguous levels from L2-S1. DDD is defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies. These DDD patients may also have up to Grade 1 spondylolisthesis or retrolisthesis at the involved level(s). This device is to be used with autogenous bone graft and/or allogenous bone graft composed of cancellous and/or corticocancellous bone. AccelFix Lumbar Expandable Cage System is to be used with supplemental fixation. Patients should have at least six (6) months of non-operative treatment prior to treatment with an intervertebral cage.

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

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
Submission date:	July 6, 2023
Contact Person:	Katherine Kim khkim@lnkbiomed.com/khkim3747@gmail.com

2. DEVICE NAME

Trade or Proprietary Name	AccelFix Lumbar Expandable Cage System
Common or Usual Name	Intervertebral Body Fusion Device, Intervertebral cage, Spacer
Regulation class / Number	ClassII, CFR 888.3080
Regulation Name	Intervertebral Body Fusion Device
Product Code	MAX
Classification Panel	Orthopedics

3. PREDICATE DEVICE

The changes to this product, the additional approach, do not affect the product's design, dimensional sizes, indication for use, material, scientific technology and manufacturing process.
The design feature and indications for use and manufacturing process for the subject device 'AccelFix Lumbar Expandable Cage System' is substantially equivalent to the predicate device.

Primary Predicate Device: AccelFix Lumbar Expandable Cage System (K190708)

4. DESCRIPTION OF THE DEVICE

The AccelFix Lumbar Expandable Cage System's implants are interbody fusion devices intended for use as an aid in spinal fixation. They are made of Titanium 6AL-4V Alloy (ASTM F136). These hollow, rectangular implants are offered in a variety of widths, lengths, heights and lordotic angles designed to adapt to a variety of patient anatomies. The implants can be expanded in height after insertion in the unexpanded state using the system instrumentation. The implants have serrations on the superior and inferior surfaces designed for fixation.

- AccelFix-XT Expandable Cage is to be implanted via transforaminal and posterior approach.
- AccelFix-XTP Expandable Cage is to be implanted via Anterior to Psoas approach and lateral Approach.
- AccelFix-XL Expandable Cage is to be implanted via lateral approach.

5. INDICATION FOR USE

AccelFix Lumbar Expandable Cage System is indicated for intervertebral body fusion procedures in skeletally mature patients with degenerative disc disease (DDD) at one or two contiguous levels from L2-S1. DDD is defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies. These DDD patients may also have up to Grade 1 spondylolisthesis or retrolisthesis at the involved level(s). This device is to be used with autogenous bone graft and/or allogenous bone graft composed of cancellous and/or corticocancellous bone. AccelFix Lumbar Expandable Cage System is to be used with supplemental fixation systems. Patients should have at least six (6) months of non-operative treatment prior to treatment with an intervertebral cage.

6. PERFORMANCE DATA

Changes made by this submission are not subject to additional mechanical testing.

The predicate AccelFix Lumbar Expandable Cage System was tested according to the ASTM F 2077, ASTM F 2267 and ASTM draft as described below.

Static compression, dynamic compression, static and dynamic shear testing according to ASTM F2077, was presented to demonstrate the substantial equivalency of the AccelFix Lumbar Expandable Cage System to the predicate devices.

- Static Axial Compression Test – ASTM F 2077 -17
- Static Compression-Shear Test - ASTM F 2077 -17
- Static Torsion Test - ASTM F 2077 -17
- Static Expulsion Test
- Static Subsidence Test – ASTM F 2267 − 04 (Reapproved 2018)/F 2077-17
- Dynamic Axial Compression Test– ASTM F 2077 -17
- Dynamic Compression-Shear Test - ASTM F 2077 -17

Bench testing to evaluate the mechanical properties of the AccelFix Lumbar Expandable Cage System showed a higher or similar mechanical value than predicate marketed devices.

7. MATERIAL

The AccelFix Lumbar Expandable Cage is manufactured from Ti-6Al-4V ELI titanium alloy (ASTM F136). This this is the same material used in the predicate devices. And additional instruments and changed instrument pieces that are patient anatomy contacting are manufactured of medical grade materials (medical-grade stainless steel, medical grade silicone) and are tissue contacting in limited-exposure duration of less than 24 hours. Only the materials that contact with tissue are considered in this regard. The additional instruments that contact tissue area during surgery are made of Stainless-Steel ASTM F 899-20(STS455, STS630, STS 304). These materials have been widely recognized to be safe materials and known to be biocompatible.

8. COMPARISON OF TECHNICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The subject and predicate devices are identical technological characteristics and there is not any new issues of safety and effectiveness. The characteristics are similar or identical between the subject and the predicate, but the data for the characteristics are as compared to the data below.

- Instruction for use (added lateral approach to AccelFix-XTP Cage)
- Design and sizes
- Expanding Mechanism
- Material (material change due to design change of Expandable Cage Inserter)
- Approach (added lateral approach to AccelFix-XTP Cage)
- Sterilization & Method
- Manufacturing process (for the subject device of Expandable Cage Inserter, the handle manufacturing process and the integrating process(assembling) of indicator module, cage inserter body and handle are excluded from the predicate device manufacturing process).

INDICATION FOR USE

Similarities	
Subject Devices	Indication for use are same
Predicate Devices K190708	

DESIGN AND SIZES OF IMPLANTS

Characteristics	Subject Devices	Predicate Devices K190708	Similarities/Differences
Design	Subject implant has the same design as predicate implant		Similar
Sizes	Subject implant has the same sizes as predicate implant		Similar
Material	Ti-6Al-4V ELI titanium alloy (ASTM F136)	Ti-6Al-4V ELI titanium alloy (ASTM F136)	Similar
Manufacturing Process	Subject implant's manufacturing process is the same as predicate implant's		Similar

INSTRUMENTS (EXPANDABLE CAGE INSERTER XTP01-0001)

Characteristics	Subject Devices	Predicate Devices K190708	Similarities/Differences
Design(changed)	The Height Indicator Module and handle are separated and excluded from the expandable cage inserter.	The indicator module, cage inserter body and handle are integrated	Difference
Material	STS 630, STS 304-tissue contact	STS 630(ASTM F 899-20) STS 304(ASTM F 899-20) STS 455(ASTM F 899-20) Ti6AL4V (ASTM F 136) Silicone	Difference
Manufacturing process	The handle and indicator module are separated and removed from the cage insert of the subject device. Therefore, the manufacturing process of the handle and indicator module and the process of integrating (assembly) the cage insert body are excluded, and the rest of the processes are the same as the predicate device manufacturing process.		Difference

ADDITIONAL INSTRUMENTS (CLASS II)

Characteristics	Material	Similarities/Differences
Subject Devices tissue contact material	ASTM F 899-20 (STS 630, STS 304, STS455) Tissue contacts materials	Similar
Predicate Devices K190708	ASTM F 899-20 (STS 630, STS 304, STS455) Tissue contacts materials	

APPROACH

Characteristics	Subject Devices	Predicate Devices K190708	Similarities/Differences
Approach AccelFix-XTP Cage	Anterior to Psoas Approach Lateral Approach.	Lateral Approach.	Difference added Lateral Approach

STERILIZATION

Subject Devices	Predicate Devices K190708	Similarities/Differences
▪ Sterile device: Gamma radiation ▪ Non-sterile device: recommended steam sterilization (autoclave sterilization)	▪ Sterile device: Gamma radiation ▪ Non-sterile device: recommended steam sterilization (autoclave sterilization)	Similar

CLEANING METHOD

Manual Cleaning Procedure: The manual cleaning procedure for subject devices changed the cleaning time from the manual cleaning procedure for predicate devices and deleted the sonicate part.

Subject Devices	Predicate Devices K190708	Similarities /Differences
(1) Soak the instrument in the tap water for 1 minute. (2) Prepare cleaning solution at the concentration (0.8%~1.6 %) suggested by the detergent manufacturer and soak the instrument in the prepared cleaning solution for 5 minutes, and then remove the contamination from the instrument surface with a soft brush. However, the operating part should be operated to clean the contamination. (3) Rinse the instrument for at least 3 minutes with tap water. However, the small diameter hole is rinsed using a syringe or the like. (4) Rinse the instrument by shaking with purified water for at least 5 minutes. (5) Wipe off water in the instruments with a clean cloth. However, compressed air can be used for the device with complex structures. (6) Prepare for storage and sterilization.	- Use the neutral pH enzyme soaking solution that has been prepared. - Completely submerge the instrument in enzyme solution and allow it to soak for 20 minutes (water temperature: follow the manufacturer's instruction). Scrub instrument using a soft-bristled brush to gently clean the device (particular attention shall be given to crevices, lumens, mated surfaces, and other hard-to-clean areas) until all visible soil has been removed. Lumens should be cleaned with a long, narrow, soft-bristled brush (i.e., pipe cleaner brush). Note: Any assembled instruments, please disassemble the parts before submerging. Note: The enzyme solution should be changed on a regular basis in order to ensure its effectiveness. - Remove the device from the enzyme solution and rinse in purified water (from one or any combination of the following processes: ultra-filter, RO, DI and/or distilled) for a minimum of 3 minutes. Thoroughly flush lumens, holes and other difficult to reach areas. - Prepare the neutral pH cleaning (detergent) solution according to the manufacturer's instructions, dilution recommendations, and temperatures and place in a sonication unit. - Completely submerge device in cleaning solution and sonicate for 10 minutes, preferably at 45-50 kHz. - Rinse instrument in purified water (from one or any combination of the following processes: ultra-filter, RO, DI and/or distilled) thoroughly for at least 3 minutes. - Repeat Steps 5 and 6 with freshly prepared cleaning solution. - Dry the instrument with a clean, disposable, absorbent, non-shedding wipe. - Visually inspect the devices under normal room lighting condition to verify all foreign debris has been removed thoroughly clean. - Verify that the devices are visually clean.	changed

Semi-auto Cleaning Procedure: Added Semi-auto cleaning procedure on subject devices		
Subject Devices	Predicate Devices K190708	Similarities /Differences
(1) Prepare cleaning solution at the concentration (0.8%~1.6 %) suggested by the detergent manufacturer and soak the instrument in the prepared cleaning solution for 20 minutes. Clean the instrument with a soft brush. (Especially, carefully wipe the gaps, interiors, and surfaces that are difficult to clean.) The inside of the instrument should be cleaned with a long, narrow, and soft brush. (2) Rinse with purified water for 3 minutes to remove the cleaning solution. Use rinsing water temperature between 35℃ and 45℃ for part and holes that are difficult to clean. (3) Immerse the product in the cleaning solution and clean using ultrasonic cleaner at 45 kHz to 50 kHz for 10 minutes. (4) Rinse with purified water for at least 3 minutes until there is no blood or contaminants. If contaminants remain, ultrasonic cleaning (step 3) and rinsing (step 4) are performed once more. (5) Wipe the instrument cleaned with a clean, absorbent disposable wipe to dry instrument. If additional drying is needed after drying step, use medical compressed air (psi 20~30) to dry it. Check that the instrument is visually cleaned.	None	Added

Auto Cleaning Procedure: Added Semi-auto cleaning procedure on subject devices		
Subject Devices	Predicate Devices K190708	Similarities /Differences
Automated washer/disinfector systems are not recommended as the sole cleaning method for complex surgical instruments. These instruments should be cleaned following the manual cleaning procedure above. An automated system may be used as a follow-up method but is not required. **CAUTION:** ・ Use of corrosive products and/or instruments including abrasive sponges and metal brushes should be avoided. ・ Visually inspect the devices under normal room lighting condition to verify all foreign debris has been removed thoroughly clean. ・ Verify that the instruments are in visually clean.	Automated washer/disinfector systems are not recommended as the sole cleaning method for complex surgical instruments. These instruments should be cleaned following the manual cleaning procedure above. An automated system may be used as a follow-up method but is not required. **CAUTION:** ・ Use of corrosive products and/or instruments including abrasive sponges and metal brushes should be avoided. ・ Visually inspect the devices under normal room lighting condition to verify all foreign debris has been removed thoroughly clean. ・ Verify that the instruments are in visually clean.	Same

9. SUBSTANTIAL EQUIVALENCE AND CONCLUSION

The subject AccelFix Lumbar Expandable Cage System have been found to be substantially equivalent to the predicate devices with respect to technical characteristics, performance, material, intended use and manufacturing process. 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 AccelFix Lumbar Expandable Cage System is substantially equivalent to the predicate devices (K190708).