



L&K Biomed Co., Ltd.  
Kihyang Kim  
RA Vice President  
#201, 202 16-25, Dongbaekjungang-ro 16 beon-gil, Giheung-gu  
Yongin-si, Republic of Korea

September 16, 2019

Re: K190708

Trade/Device Name: AccelFix Lumbar Interbody Fusion Cage System  
Regulation Number: 21 CFR 888.3080  
Regulation Name: Intervertebral Body Fusion Device  
Regulatory Class: Class II  
Product Code: MAX  
Dated: August 13, 2019  
Received: August 15, 2019

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 (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](mailto:DICE@fda.hhs.gov)) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

for Melissa Hall  
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

## Indications for Use

510(k) Number (if known)

K190708

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 allogeneous 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:

### 1 Manufacturer

<b>Submitter:</b>	Gook Jin Kang L&K BIOMED Co., Ltd.
	#201, 202 16-25, Dongbaekjungang-ro 16 beon-gil Giheung-gu, Yongin-si, Gyeonggi-do, 17015, Korea Phone. 82-2-6717-1983/ FAX .82-2-6717-1949
Contact Person:	Kihyang Kim <a href="mailto:khkim@lnkbiomed.com">khkim@lnkbiomed.com</a> / <a href="mailto:khkim3747@gmail.com">khkim3747@gmail.com</a>

### 2. Device Identification

Trade Name:	AccelFix Lumbar Expandable Cage System
Common Name:	Intervertebral Body Fusion Cage
Product Code:	MAX
Classification:	Class II
Classification Name:	Intervertebral body fusion device
Regulation No.	21 CFR 888.3080
Classification Pane	Orthopedic

### 3. Predicate or legally marketed devices which are substantially equivalent.

The AccelFix Lumbar Expandable Cage System has undergone a comprehensive battery of non-clinical testing, including chemical and physical testing. Testing has shows the device is as safe and effective for its intended use as a predicate device and supports a determination of substantial equivalence.

The AccelFix Lumbar Expandable Cage System met all pre-defined acceptance criteria and, in tests where it was compared to either AccelFix Lumbar Expandable Cage System the predicate devices, was found to not represent a new worst case.

Overall, the results of the performance bench tests support the substantial equivalence of the Subject device.

The design feature and indications for use for the subject device ‘AccelFix Lumbar Expandable Cage System’ is substantially equivalent to the following predicate(s);

- 1) Primary Predicate Device: ProLift® Expandable System (K173182)
- 2) Additional Predicate Devices: Concorde Lift Expandable Cage(171425)  
LnK Lumbar Interbody Fusion Cage System (K110783, K120063, K121096, K151140, K181380)

### 4 Materials

AccelFix Lumbar Expandable Cage System 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**

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.
- AccelFix-XL Expandable Cage is to be implanted via lateral approach.

**6. Intended 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 allogeneous 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.

**7. Performance –Bench testing**

The AccelFix Lumbar Expandable Cage System was tested according to the ASTM F 2077, and ASTM F 2267 as noted 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.

**8. Summary of Technology Characteristics**

AccelFix Lumbar Expandable Cage System is substantially equivalent to the predicate systems in terms of design, materials, indications for use and sizing.

**9. Substantial Equivalence:**

AccelFix Lumbar Expandable Cage System was shown to be substantially equivalent to the predicate devices in indications for use, design, function, materials used and mechanical performance.

**10. Conclusion**

The information presented demonstrates the substantial equivalency of the AccelFix Lumbar Expandable Cage System to the predicate devices.