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

July 28, 2020

Re: K192481
Trade/Device Name: AccelFix Lumbar Plate System
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal Intervertebral Body Fixation Orthosis
Regulatory Class: Class II
Product Code: KWQ
Dated: July 11, 2020
Received: July 14, 2020

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) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

for

Colin O'Neill, M.B.E.
Acting 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K192481

Device Name
AccelFix Lumbar Plate System

Indications for Use *(Describe)*

The AccelFix Lumbar Plate System is indicated for use via the anterior, lateral or anterolateral surgical approach above the bifurcation of the great vessels or via the anterior surgical approach, below the bifurcation of the great vessels as an adjunct to fusion. This system is indicated in the treatment of lumbar and lumbosacral (L1-S1) spine instability as a result of fracture (including dislocation and subluxation), tumor, degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies), pseudoarthrosis, spondylolysis, scoliosis, spondylolisthesis, lordotic deformities of the spine, spinal stenosis, or a failed previous spine surgery.

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

Submitter:	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 khkim@lnkbiomed.com/ khkim3747@gmail.com
Date	October 27, 2019

2. Device Identification

Trade Name:	AccelFix Lumbar Plate System
Common Name:	Spinal Fixation Appliances
Product Code:	KWQ
Classification:	Class Ⅱ
Classification Name:	Spinal intervertebral body fixation orthosis
Regulation No.	21 CFR 888.3060
Classification Pane	Orthopedic

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

The AccelFix Lumbar Plate System is undergone a comprehensive battery of non-clinical testing, including chemical, physical. The testing supports a determination of substantial equivalence. The AccelFix Lumbar Plate System met all pre-defined acceptance criteria and, in tests where it was compared to either AccelFix Lumbar Plate System the predicate or reference device, 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 Plate System' is substantially equivalent to the following predicate(s);

1) Primary Predicate Device: LITe Plate System (Stryker/ K142699)
2) Additional Predicate Devices: Trinica® Anterior Lumbar Plate System (Zimmer Spine K143626)

4 Materials

AccelFix Lumbar Plate 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 Plate System's implants are Lumbar Plate System intended for use as an aid in spinal fixation. They are made of Titanium 6AL-4V Alloy (ASTM F136). The AccelFix Lumbar Plate System consists of a variety of shapes and sizes of plates and screws.

The plate has been designed to include spikes for added stability and alignment during screw insertion. The plates feature a curvature for anatomic fit. The diameter of screw is available from 5.5 to 6.0 mm and the length from 20 to 55 mm.

6. Indications for Use

The AccelFix Lumbar Plate System is indicated for use via the anterior, lateral or anterolateral surgical approach above the bifurcation of the great vessels or via the anterior surgical approach, below the bifurcation of the great vessels as an adjunct to fusion. This system is indicated in the treatment of lumbar and lumbosacral (L1-S1) spine instability as a result of fracture (including dislocation and subluxation), tumor, degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies), pseudoarthrosis, spondylolysis, scoliosis, spondylolisthesis, lordotic deformities of the spine, spinal stenosis, or a failed previous spine surgery.

7. Performance –Bench testing

The AccelFix Lumbar Plate System was tested according to the ASTM F 1717-18.

1) Static Compression Bending Test - ASTM F1717-18
2) Static Tension Bending Test - ASTM F1717-18
3) Static Torsional Test - ASTM F1717-18
4) Dynamic Compression Bending Test - ASTM F1717-18

Static compression, Static tensile, Static torsion and dynamic compression according to ASTM F 1717-18 was presented to demonstrate the substantial equivalency of the AccelFix Lumbar Plate System to the predicate devices.

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

8. Summary of Technology Characteristics

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

9. Substantial Equivalence:

AccelFix Lumbar Plate 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 Plate System to the predicate devices.