October 20, 2020

L&K BIOMED Co., Ltd.
Minju Choi
Official Correspondent
#201, 202 16-25, Dongbaekjungang-ro 16 beon-gil,
Giheung-gu
Yongin-si, Gyeonggi-do 17015
Korea

Re: K200794
Trade/Device Name: 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: September 21, 2020
Received: September 21, 2020

Dear Ms. Choi:

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,

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)*
K200794

Device Name
AccelFix Spinal Fixation System

Indications for Use *(Describe)*
The AccelFix Spinal Fixation System is non-cervical spinal fixation devices intended for use as posterior pedicle screw fixation systems (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 intended as an adjunct to fusion for all of the following indications: 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.

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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:	L&K BIOMED Co., Ltd.
	#201, 202 16-25, Dongbaekjungang-ro 16 beon-gil, Giheung-gu, Yongin-si, Gyeonggi-do, 17015, Korea
	Phone. +82-10-5477-0325
Contact Person:	Minju Choi e-mail: jung9844@lnkbiomed.com
Date prepared	March 25, 2020

2. Device Identification

Trade Name	AccelFix Spinal Fixation System
Common Name	Pedicle screw spinal system
Product Code	NKB, KWP, KWQ
Regulatory Class	Class II
Classification Name	Thoracolumbosacral pedicle screw system Spinal interlaminal fixation orthosis Spinal intervertebral body fixation orthosis
Regulation No.	21 CFR 888.3070, 21 CFR 888.3050, 21 CFR 888.3060

3. Predicate or legally marketed devices which are substantially equivalent

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

Primary Predicate: AccelFix Spinal Fixation System (K182544)

4. Description of the Device

The AccelFix Spinal Fixation System consists of screws, rods, crosslinks, set screws, connectors and hooks. The AccelFix Spinal Fixation System is comprised of six different groupings;

AccelFix-S	1) Mono Axial Screw 2) Reduction Mono Axial Screw 3) Poly Axial Screw 4) Reduction Poly Axial Screw
AccelFix-DS	1) Mono Axial Screw 2) Reduction Mono Axial Screw 3) Poly Axial Screw 4) Reduction Poly Axial Screw
AccelFix-SS	1) Mono Axial Screw 2) Reduction Mono Axial Screw 3) Poly Axial Screw 4) Reduction Poly Axial Screw
AccelFix-MIS	1) Percutaneous Poly Screw Closed Type 2) Percutaneous Poly Screw Open Type
AccelFix -SAI Screw	1) Poly Axial Screw (1) Smooth Shank- Non cannulated, cannulated (2) Full Thread- Non cannulated, cannulated 2) Reduction Poly Axial Screw (1) Smooth Shank- Non cannulated, cannulated (2) Full Thread- Non cannulated, cannulated
Accessory	1) Rod 2) Crosslink 3) Set screw 4) Connector 5) Hook

5. Materials

The components of this system are manufactured of Titanium Alloy (Titanium-6Aluminum-4Vanadium ELI, per ASTM F136) or CoCrMo alloy (Cobalt-28Chromium-6Molybdenum, per ASTM F1537).

6. Indication for use

The AccelFix Spinal Fixation System is non-cervical spinal fixation devices intended for use as posterior pedicle screw fixation systems (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 intended as an adjunct to fusion for all of the following indications: 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 Testing

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 AccelFix Spinal Fixation System. Therefore, we substitute mechanical test data of additional components of AccelFix Spinal Fixation System with the predicate device (K182544).

ASTM F1717-15 (Static compression test, Static tension test, Static torsion test, Fatigue test)
ASTM F1798-13 (Static cantilever test, axial grip test, static head pullout test)
ASTM F543-17 (Axial pullout test)

8. Summary of Technology Characteristics

AccelFix Spinal Fixation System are substantially equivalent to the predicate devices in terms of design, materials and indications for use.

9. Substantial Equivalence

AccelFix Spinal Fixation System were shown to be substantially equivalent to the predicate devices in indications for use, design, function and materials used.

10. Conclusion

The AccelFix Spinal Fixation System is substantially equivalent to the predicate device (K182544).