May 28, 2019

L&K BioMed Co., Ltd.
Ms. Jihyeon Seo
Regulatory Affairs Associate
#201, 202 16-25, Dongbaekjungang-ro 16 beon-gil,
Giheung-gu, Yongin-si, Gyeonggi-do, 17015
KOREA

Re: K182544
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, KWQ, KWP
Dated: May 9, 2019
Received: May 13, 2019

Dear Ms. Seo:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/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
CAPT Raquel Peat, PhD, MPH, USPHS
Director
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)*
K182544

Device Name
AccelFix Spinal Fixation System

Indications for Use *(Describe)*
The AccelFix Spinal Fixation System is intended for use as a posterior pedicle screw system (T1-S2/ilium), or as an anterolateral fixation system (T8-L5), to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar and sacral spine: 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. Submitter:

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Giheung-gu, Yongin-si, Gyeonggi-do, 17015, Korea
Phone. 82-2-6717-1983
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Contact Person: Jihyeon Seo

Date prepared: September 14, 2018

2. Device Identification

Trade Name	AccelFix Spinal Fixation System
Common Name	Pedicle screw spinal system
Product Code	NKB, KWQ, KWP
Regulatory Class	II
Classification Name	Thoracolumbosacral pedicle screw system (21 CFR 888.3070) Spinal intervertebral body fixation orthosis (21 CFR 888.3060) Spinal interlaminal fixation orthosis (21 CFR 888.3050)

3. Predicate or legally marketed devices which are substantially equivalent

The design feature and indications for use for the subject device 'AccelFix Spinal Fixation System' are substantially equivalent to the following predicate(s):

- **Primary predicate device:** OpenLoc-L Spinal Fixation System (K171813),
- **Additional predicate device:** Synergy Spinal System VLS Closed/Opened (K974749,K000236, K011437), Anyplus Spinal Fixation System (K172546), Perfix Spinal System (K091725), Optima Spinal System (K031585), GSS Pedicle Screw System (K053573) and PathLoc-L MIS Spinal System (K161766)

4. Description of the Device

AccelFix Spinal Fixation System consists of screws, rods, crosslinks, set screws, connectors and hooks. 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). The AccelFix Spinal Fixation System is comprised of five 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
Accessory	1) Rod 2) Crosslink 3) Set screw 4) Connector 5) Hook 6) MIS Rod

5. Indication for use

The AccelFix Spinal Fixation System is intended for use as a posterior pedicle screw system (T1-S2/ilium), or as an anterolateral fixation system (T8-L5), to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar and sacral spine: 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)

6. Comparison of the technology characteristics of the device to predicate and legally marketed devices

The AccelFix Spinal Fixation System shares technological characteristics similar to the predicate device. These characteristics include similar design, the same materials, substantially equivalent performance characteristics and the same intended use.

7. Performance Data

The AccelFix Spinal Fixation System was tested for the following tests according to the FDA recognized standards;

ASTM F1717
Static compression test, Static torsion test, Fatigue compression test

ASTM F1798
Static Cantilever test, Static head pullout test, Axial grip force test

ASTM F543
Axial pullout test

8. Conclusion

The AccelFix Spinal Fixation System is substantially equivalent to the predicate device(s) (K171813, K974749, K000236, K011437, K172546, K091725, K031585, K053573, K161766).