June 23, 2022

JMT Co., Ltd
% Priscilla Chung
Regulatory Affairs Consultant
Lk Consulting Group USA, Inc.
1150 Roosevelt STE 200
Irvine, California 92620

Re: K201788
Trade/Device Name: EDEN Spinal Fixation System
Regulation Number: 21 CFR 888.3070
Regulation Name: Thoracolumbosacral Pedicle Screw System
Regulatory Class: Class II
Product Code: NKB
Dated: June 14, 2022
Received: June 16, 2022

Dear Priscilla Chung:

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.
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)*
K201788

Device Name
EDEN Spinal Fixation System

Indications for Use *(Describe)*
The EDEN Spinal Fixation System is intended to provide immobilization and stabilization of the posterior, non- cervical spine as an adjunct to fusion in skeletally mature patients for the following indications: degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, trauma (i.e., fracture or dislocation), spinal stenosis, curvatures (i.e., scoliosis, kyphosis and/or lordosis), tumor, pseudarthrosis, and/or failed previous fusion.

The EDEN Spinal Fixation System can be used in an open approach and a percutaneous approach with MIS instrumentation.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary

This summary of 510(K) information is being submitted in accordance with requirements of 21 CFR Part 807.92.

Date: 6/22/2022

1. Submitter

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2. U.S Agent/Contact Person

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3. Device

- Trade Name: EDEN Spinal Fixation System
- Common Name: Non-Sterile Spinal Fixation System
- Classification Name: Thoracolumbosacral pedicle screw system
- Product Code: NKB
- Classification regulation: 21CFR 888.3070

4. Predicate Device:

GALAXY MIS Screw System by BM KOREA Co., Ltd. (K143110)

5. Description:

The EDEN Spinal Fixation System is a pedicle screw and rod system intended for immobilization and stabilization of the spine as an adjunct to fusion. The EDEN Spinal Fixation System consists of pedicle screws, rods, cross links, and set screws that can be used via percutaneous surgical approach. The components are available in a variety of designs and sizes in order to accommodate patient anatomy and are fabricated from titanium alloy (ASTM F136). The implants will be provided non-sterile.

The EDEN Spinal Fixation System also offer a wide variety of instrument that range from bone awls to screwdrivers.
They are made of various grades of stainless steel and aluminum alloys. All the items are supplied non-sterile and must be sterilized prior to use. We believe orthopedic instrument is Class I, 510k exempt. The information here is provided for informational purpose only.

6. Indication for use:

The EDEN Spinal Fixation System is intended to provide immobilization and stabilization of the posterior, non- cervical spine as an adjunct to fusion in skeletally mature patients for the following indications: degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, trauma (i.e., fracture or dislocation), spinal stenosis, curvatures (i.e., scoliosis, kyphosis and/or lordosis), tumor, pseudarthrosis, and/or failed previous fusion.

The EDEN Spinal Fixation System can be used in an open approach and a percutaneous approach with MIS instrumentation.

7. Basis for Substantial Equivalence

The subject device is substantially equivalent to GALAXY MIS Screw System (K143110) by BM KOREA Co., Ltd.

Substantial Equivalence Discussion

The subject device is substantially equivalent to the GALAXY MIS Screw System by BM KOREA Co., Ltd. (K143110).

The devices have the same indications for use and use the same materials. The designs are similar. We have conducted the performance tests and the results support that the subject device is substantially equivalent to the predicate device.

8. Non-Clinical Testing

- Sterilization validation testing per ISO 17665-1 and 17665-2
- Biocompatibility testing per ISO 10993
- Static flexion/extension testing per ASTM F1798
- Foam block pullout testing per ASTM F543
- Static and dynamic compression bending, static torsion, and static tension testing per ASTM F1717

9. Conclusion

The subject device and the predicate device have the same intended use and have similar technological characteristics. Based on the similarities and the test results, we conclude that the EDEN Spinal Fixation System is substantially equivalent to the predicate device.