JMT Co., Ltd.
℅ Dave Kim
Medical Regulatory Affairs
Mtech Group
7505 Fannin St. Suite 610
Houston, Texas 77054

June 15, 2023

Re: K230762
Trade/Device Name: EDEN Spinal Fixation MIS System
Regulation Number: 21 CFR 888.3070
Regulation Name: Thoracolumbosacral Pedicle Screw System
Regulatory Class: Class II
Product Code: NKB
Dated: May 12, 2023
Received: May 18, 2023

Dear Dave 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,

Eileen Cadel -S
Digitally signed by Eileen Cadel -S
Date: 2023.06.15 13:31:33 -04'00'
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)*
K230762

Device Name
EDEN Spinal Fixation MIS System

Indications for Use *(Describe)*
The EDEN Spinal Fixation MIS 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 MIS System can be used in an open approach and a percutaneous approach.

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

The following 510(k) summary is being submitted as required by 21 CFR Part 807.92;

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Date Prepared: February 23, 2023

Device Identification

Device Trade Name	EDEN Spinal Fixation MIS System
Common Name	Pedicle Screw Spinal System
Classification Name, Number	Thoracolumbosacral Pedicle Screw System (21 CFR 888.3070)
Device Classification	II
Product Code	NKB

Predicate or legally marketed devices which are substantially equivalent
Primary predicate device: K201788, "EDEN Spinal Fixation System", manufactured by "JMT Co., Ltd."

Device Description
The purpose of this special 510(k) submission is to add MIS components and instruments to the previously cleared EDEN Spinal Fixation System. The EDEN Spinal Fixation MIS System will allow surgeons to build a spinal implant construct to stabilize and promote spinal fusion. The EDEN Spinal Fixation MIS System implant components are supplied non-sterile, single use and fabricated from titanium alloy (Ti-6AI- 4V ELI) that conforms to ASTM F136. Various sizes of these implants are available. Specialized instruments are available for the application and removal of the EDEN Spinal Fixation MIS System. The EDEN Spinal Fixation MIS System will also offer a wide variety of instruments that range from bone awls to occipital screwdrivers. These instruments will be made from various grades of stainless steel with aluminum alloy being used in a few handles. All items are supplied "NON-STERILE" and must be sterilized prior to use. The orthopedic instruments are Class I, 510k exempt, and discussed here for informational purpose only.

Indications for Use
The EDEN Spinal Fixation MIS 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 MIS System can be used in an open approach and a percutaneous approach.

Non-clinical Test Conclusion
The following properties were tested based on the referenced standards. All the test results support substantial equivalence to the predicate devices.

○ ASTM F1717-18 Standard Test Methods for Spinal Implant Constructs in a Vertebrectomy Model
- Static compression bending
- Static tension bending
- Static torsion
- Dynamic compression bending

○ FDA Guidance Document – Use of International Standard ISO 10993-1, Biological Evaluation of Medical Devices - Part 1: Evaluation and Testing within a Risk Management Process
○ ISO 10993-1 Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
○ ISO 10993-3 Biological evaluation of medical devices - Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity
○ ISO 10993-5 Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity
○ ISO 10993-6 Biological evaluation of medical devices, Tests for local effects after implantation.
○ ISO 10993-10 Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization
○ ISO 10993-11 Biological evaluation of medical devices - Part 11: Tests for systemic toxicity
○ ISO 10993-23 Biological evaluation of medical devices - Part 23: Tests for irritation
○ ISO 10993-18 Biological evaluation of medical devices, Chemical characterization of medical device materials within a risk management process

Bench test results conclude that EDEN Spinal Fixation MIS System is substantially equivalent to the predicate devices for its intended use.

Technological Characteristics and Substantial Equivalence

The EDEN Spinal Fixation MIS System does not have a new intended use. It shows the exact same raw materials and specifications in terms of poly screw angulation, as the predicate device.

The **EDEN Spinal Fixation MIS System** and **EDEN Spinal Fixation System (K201788)** have been demonstrated as substantially equivalent in dimensional and performance criteria to the primary predicate device.

Conclusion	Based on the testing results, JMT Co., Ltd. concludes that the subject device is substantially equivalent to the predicate device.