May 26, 2023

Met One Technologies, LLC
Adrian Carbonell
Chief Operating Officer
513 W. San Antonio Ave, Suite C
El Paso, Texas 79901

Re: K230851
Trade/Device Name: Kodiak Lumbar Spacer System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: MAX
Dated: March 22, 2023
Received: March 28, 2023

Dear Adrian Carbonell:

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,

Katherine D. Kavlock -S

for
Brent Showalter, Ph.D.
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)*
K230851

Device Name
Kodiak Lumbar Spacer System

Indications for Use *(Describe)*
The Kodiak Lumbar Spacer System is indicated for spinal fusion procedures in skeletally mature patients with degenerative disc disease (DDD) at one or two contiguous levels in the lumbar spine (L2-S1) with up to Grade 1 spondylolisthesis or retrolisthesis at the involved level(s). DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. Patients with previous non-fusion spinal surgery at the involved level may be treated with the Kodiak Lumbar Spacer System. Patients must have undergone a regimen of at least six (6) months of nonoperative treatment prior to being treated with the Kodiak Lumbar Spacer System.

The Kodiak Lumbar Spacer System is designed for use with autogenous bone graft. The system is also intended to be used with supplemental fixation systems that are cleared by the FDA for use in the lumbar spine.

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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5. 510(K) SUMMARY

Date: March 22, 2023

Sponsor: Met One Technologies, LLC
513 W. San Antonio Ave Ste. C
El Paso, TX 79901
(915)373-3855

Sponsor Contact: Adrian Carbonell, Chief Operating Officer

Proposed Trade Name: Kodiak Lumbar Spacer System

Common Name: Intervertebral Fusion Device with Bone Graft, Lumbar

Classification: Class II per 21 CFR 888.3080

Product Codes: MAX

Classification Panel: Division of Orthopedic Devices

Device Description: The Met One Technologies Kodiak Lumbar Spacer System is a lumbar intervertebral body fusion device that is implanted into the vertebral body space to improve stability of the spine while supporting fusion. The Kodiak Lumbar Spacer System may be implanted bilaterally using a posterior (PLIF) approach, or as a single device employing a transformational (TLIF) approach. The implants have a central endplate window to permit packing of autograft and/or allograft bone, teeth on the superior and inferior surfaces, and lateral windows for radiographic visualization. The implants are additively manufactured from Ti-6Al-4V ELI and are available in a variety of heights, footprints, and lordotic configurations to suit individual patient anatomy.

Indications for Use: The Kodiak Lumbar Spacer System is indicated for spinal fusion procedures in skeletally mature patients with degenerative disc disease (DDD) at one or two contiguous levels in the lumbar spine (L2-S1) with up to Grade 1 spondylolisthesis or retrolisthesis at the involved level(s). DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. Patients with previous non-fusion spinal surgery at the involved level may be treated with the Kodiak

Lumbar Spacer System. Patients must have undergone a regimen of at least six (6) months of nonoperative treatment prior to being treated with the Kodiak Lumbar Spacer System.

The Kodiak Lumbar Spacer System is designed for use with autogenous bone graft. The system is also intended to be used with supplemental fixation systems that are cleared by the FDA for use in the lumbar spine.

Materials: The Kodiak Lumbar Spacer System is comprised of a family of implants that has bodies additively manufactured from Ti-6Al-4V Eli, in compliance with ASTM F3001.

Primary Predicate: AUDERE Lumbar Spacer System (Met One Technologies, LLC – K160699, K193457)

Additional Predicates: Foundation 3D Interbody Lumbar Cage (CoreLink, LLC – K162496)
Standalone ALIF Interbody Fusion Device (Eminent Spine, LLC – K221936)
Kodiak C Spinal Implant System (Met One Technologies, LLC – K222806)

Performance Data: The Kodiak Lumbar Spacer System has been evaluated in accordance with the following test modes and demonstrated substantial equivalence:

- Static Compression per ASTM F2077
- Dynamic Compression per ASTM F2077
- Static Compression-Shear per ASTM F2077
- Dynamic Compression-Shear per ASTM F2077
- Subsidence per ASTM F2267
- Expulsion

Technological Characteristics: The Kodiak Lumbar Spacer System possesses the same technological characteristics as one or more of the predicate devices. These include:

- Indications for use
- Operating principle
- Materials of manufacture (Ti-6Al-4V Eli)
- Sterilization (provided nonsterile with instruction for sterilization)
- Basic design (similar height, width, depth, and lordosis)

– Graft containment area

Therefore, the fundamental scientific technology of the Kodiak Lumbar Spacer System is the same as the previously cleared devices.

Conclusion: The Kodiak Lumbar Spacer System possesses the same intended use and technological characteristics as the predicate devices. Therefore, the Kodiak Lumbar Spacer System is substantially equivalent for its intended use.