February 18, 2020

K2M, Inc.
% Ms. Megan Callanan
Regulatory Affairs Associate
Stryker
2 Pearl Court
Allendale, New Jersey 07401

Re: K193203
Trade/Device Name: MOJAVE Expandable Interbody System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: MAX
Dated: January 17, 2020
Received: January 21, 2020

Dear Ms. Callanan:

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,

Brent L. Showalter, PhD
Assistant Director (Acting)
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K193203

Device Name
MOJAVE Expandable Interbody System

Indications for Use *(Describe)*

The MOJAVE Expandable Interbody System implants are intervertebral body fusion devices indicated for use with autograft and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft when used as an adjunct to fusion in patients with degenerative disc disease (DOD) at one level or two contiguous levels from L2 to S1. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The DDD patients may also have up to Grade I spondylolisthesis or retrolisthesis at the involved level(s). These patients should be skeletally mature and have six months of nonoperative therapy. Additionally, the MOJAVE lumbar implants can be used as an adjunct to fusion in patients diagnosed with degenerative scoliosis. MOJAVE lumbar implants are intended to be used with supplemental spinal fixation systems that have been cleared for use in the lumbosacral 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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510(k) Summary: MOJAVE Expandable Interbody System	
Submitter:	K2M, Inc. Hope Parkway SE Leesburg, VA 20175
Contact Person :	Name: Megan Callanan Phone: (551)262-2429 Email: megan.callanan1@stryker.com
Date Prepared:	11/19/2019
Trade Name:	MOJAVE Expandable Interbody System
Common Name:	Intervertebral Fusion Device with Bone Graft
Proposed Class:	Class II
Classification Name:	lntervertebral Fusion Device with Bone Graft, lumbar
Regulation Number:	21 CFR 888.3080
Product Code:	MAX
Predicate Devices:	Primary Predicate: MOJAVE Expandable Interbody System (K171097) Additional Predicate: MOJAVE Expandable Interbody System (K163364)
Device Description:	The MOJAVE Expandable Interbody System is comprised of expandable titanium implants designed to allow for intraoperative adjustment to aid the surgeon in matching implant fit to the vertebral anatomy in the lumbar spine. The implants have titanium endplates designed to allow for bone ingrowth and engagement with the vertebral body end plates. The implants are manufactured from medical grade titanium alloy (ASTM F1472, ASTM F136, ASTM F3001) and cobalt chromium alloy (ASTM F1537) and are available in a variety of heights to accommodate anatomical variations.
Indications for Use:	The MOJAVE Expandable lnterbody System implants are intervertebral body fusion devices indicated for use with autograft and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft when used as an adjunct to fusion in patients with degenerative disc disease (DOD) at one level or two contiguous levels from L2 to S1. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The DDD patients may also have up to Grade I spondylolisthesis or retrolisthesis at the involved level(s). These patients should be skeletally mature and have six months of nonoperative therapy. Additionally, the MOJAVE lumbar implants can be used as an adjunct to fusion in patients diagnosed with degenerative scoliosis. MOJAVE lumbar implants are intended to be used with supplemental spinal fixation systems that have been cleared for use in the lumbosacral spine.

510(k) Summary: MOJAVE Expandable Interbody System	
Technological Comparison to Predicate	The proposed MOJAVE Expandable Interbody System incorporates minor modifications to the system to enhance user experience. The enhancements were compared to the predicate system and were found to be comparable in design, function, intended use, materials, and size.
Non-clinical Performance Evaluation	A risk assessment, including benchtop and mechanical testing, was conducted to confirm that the subject MOJAVE Expandable Interbody System does not introduce new issues of safety or effectiveness.
Conclusion	There are no significant differences between the MOJAVE Expandable Interbody System and other devices currently being marketed which would adversely affect the use of the product. Therefore, the MOJAVE Expandable Interbody System is substantially equivalent to the predicate system.