DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

May 10, 2017

K2M, Inc.
Nancy Giezen
Manager Regulatory Affairs
600 Hope Parkway SE
Leesburg, Virginia 20175

Re: K171097
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: April 11, 2017
Received: April 13, 2017

Dear Ms. Giezen:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K171097

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 (DDD) 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.

510(k) Summary
MOJAVE Expandable Interbody System
K2M, Inc.

Submitter

K2M, Inc.
600 Hope Pkwy SE
Leesburg, VA 20175

Contact Person: Nancy Giezen
Telephone: (571) 919-2000
Date Prepared: 5/8/2017

Classification

Trade Name:	MOJAVE Expandable Interbody System
Common Name:	Intervertebral Fusion Device with Bone Graft
Regulatory Class:	Class II

Classification Name(s):
Intervertebral Fusion Device with Bone Graft, lumbar (21 CFR 888.3080, Product Code: MAX)

Predicate Device(s)

Primary Predicate:
K2M 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 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 (DDD) 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.

Technological Comparison to Predicate(s)
The MOJAVE Expandable Interbody System was compared to predicate systems and was found to be comparable to these systems in design, function, intended use, materials, and size.

Non-clinical Performance Evaluation
The worst case MOJAVE Expandable Interbody System implants were previously tested in static compression, static torsion, static compression shear and dynamic compression (per ASTM F2077), subsidence (per ASTM F2267) and expulsion. Confirmatory (static and dynamic) mechanical testing and simulated use (cadaver) testing was performed on the subject device verifying that the subject devices were not a new worst case. In addition, bacterial endotoxin testing (BET), also known as limulus amebocyte lysate (LAL) testing, was conducted in accordance with ANSI/AAMI/ST72:2011.

Conclusion
There are no significant differences between the MOJAVE spacers and other devices currently being marketed which would adversely affect the use of the product. Therefore the MOJAVE Expandable Interbody System implants are substantially equivalent to predicate devices.