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

August 3, 2018

Re: K180777
Trade/Device Name: K2M Expandable Interbody System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: MAX
Dated: June 6, 2018
Received: June 7, 2018

Dear Nancy 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. 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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/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 Showalter -S

for 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K180777

Device Name

K2M Expandable Interbody System

Indications for Use *(Describe)*

The K2M Expandable Interbody System is indicated for intervertebral body fusion of the spine in skeletally mature patients. The System is designed for use with autogenous and/or allogeneic bone graft comprised of cancellous and/or corticocancellous bone graft to facilitate fusion and supplemental internal spinal fixation systems cleared by the FDA for use in the thoracolumbar spine. The devices are to be used in patients who have had at least six months of non-operative treatment. The K2M Expandable Interbody System is intended for use in interbody fusions in the thoracic spine from T1 to T12 and at the thoracolumbar junction (T12-L1), and is intended for use in the lumbar spine, from L1 to S1, for the treatment of symptomatic disc degeneration (DDD) or degenerative spondylolisthesis at one or two adjacent levels, including thoracic disc herniation (with myelopathy and/or radiculopathy with or without axial pain). DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The K2M Expandable Interbody System can be used as an adjunct to fusion in patients diagnosed with multilevel degenerative scoliosis.

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
K2M 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: 3/23/2018

Classification

Trade Name:	K2M 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, PHM)

Predicate Device(s)
Primary Predicate:
K2M MOJAVE Expandable Interbody System (K163364)

Additional Predicates:
NuVasive MLX- Medial Lateral Expandable Lumbar Interbody System, AP Expandable XLIF System (K173025)

Device Description
The K2M 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 engagement with the vertebral body end plates. The implants are manufactured from medical grade titanium alloy (ASTM F136)

Indications for Use
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herniation (with myelopathy and/or radiculopathy with or without axial pain). DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The K2M Expandable Interbody System can be used as an adjunct to fusion in patients diagnosed with multilevel degenerative scoliosis.

Technological Comparison to Predicate(s)

The K2M 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 K2M Expandable Interbody System implants were tested in static compression, static torsion, static compression shear and dynamic compression (per ASTM F2077), subsidence (per ASTM F2267) and expulsion and determined to be equivalent to predicate devices. 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 these spacers and other devices currently being marketed which would adversely affect the use of the product. Therefore the K2M Expandable Interbody System implants are substantially equivalent to predicate devices.