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

Re: K171832
  Trade/Device Name: Range/Denali/Mesa Spinal System
  Regulation Number: 21 CFR 888.3070
  Regulation Name: Thoracolumbosacral pedicle screw system
  Regulatory Class: Class II
  Product Code: NKB, KWP, KWQ
  Dated: June 19, 2017
  Received: June 20, 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 (DICE) 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 (DICE) at its toll-free number (800) 638-2041 or
(301) 796-7100 or at its Internet address

Sincerely,

Ronald P. Jean -S for

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure
Device Name
Range/Denali/Mesa Spinal System

Indications for Use (Describe)
RANGE /DENALI/MESA and SMALL STATURE and ARI are cleared for the following indications: Non-cervical fixation as an adjunct to fusion 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.

Except for hooks, when used as an anterolateral thoracic/lumbar system the RANGE Spinal System may also be used for the same indications as an adjunct to fusion.

Except for the ARI staples, the RANGE Spinal System is indicated as an adjunct to fusion to treat adolescent idiopathic scoliosis when used for posterior non-cervical fixation in pediatric patients. The RANGE Spinal System for pediatric use is intended to be used with autograft and/or allograft. Pediatric pedicle screw fixation is limited to a posterior approach.
510(k) SUMMARY
Range/Denali/Mesa Spinal System
K2M, Inc.

Submitter
K2M, Inc.  Contact Person: Nancy Giezen
600 Hope Parkway SE  Telephone: 571 919-2168
Leesburg, VA 20175  Date Prepared: 09/14/2017

Classification
Trade Name: Range/Denali/Mesa Spinal System
Common Name: Spinal Fixation System
Regulatory Class: Class II

Classification Name(s):
Thoracolumbosacral Pedicle Screw System (21 CFR 888.3070, Product Codes: NKB)
Spinal Intervertebral body fixation Orthosis (21 CFR 888.3060, Product Code: KWQ)
Spinal Interlaminal fixation Orthosis (21 CFR 888.3050, Product Code: KWP)

Predicate Device(s)
Primary Predicates:
K2M Range/Denali/Mesa Spinal System (K141873)

Additional Predicates:
K2M Range/Denali/Mesa Spinal System (K070229, K120099, K121630, K140765)
Medicrea PASS LP (K083810)

Device Description
The Range/Denali/Mesa Spinal System is a top-loading, multiple component, posterior (thoracic-lumbar) spinal fixation system consisting of pedicle screws, rods, hooks and rod connectors. The purpose of this 510(k) is to add Mesa Hook-Claws to the system.

Function: The system functions as a spinal fixation device to provide support and stabilization of the posterior thoracic and lumbar spine.

Indications For Use
RANGE/DENALI/MESA including SMALL STATURE and ARI are cleared for the following indications:

Non-cervical fixation as an adjunct to fusion 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; pseudoarthrosis; and/or failed previous fusion.

Except for hooks, when used as an anterolateral thoracic/lumbar system the RANGE/DENALI/MESA Spinal System may also be used for the same indications as an adjunct to fusion.

Except for the ARI staples, the RANGE/DENALI/MESA Spinal System is indicated as an adjunct to fusion to treat adolescent idiopathic scoliosis when used for posterior non-cervical fixation in pediatric patients. The RANGE/DENALI/MESA Spinal System for pediatric use is intended to be used with autograft and/or allograft. Pediatric pedicle screw fixation is limited to a posterior approach.

**Technological Comparison to Predicate(s)**
The Range/Denali/Mesa Spinal System was compared to predicate systems and the design features, materials and sizes were found to be substantially the same as these systems.

**Non-clinical Performance Evaluation**
Mechanical testing in accordance with ASTM F1717 (including static torsion, static compression and dynamic compression bending) was conducted on constructs representing the worst case components. The test results revealed that the proposed implants were substantially the same as the predicate devices. The results of bacterial endotoxin testing were also provided to support substantial equivalence.

**Conclusion**
There are no significant differences between the Range/Denali/Mesa System and other systems currently being marketed which would adversely affect the use of the product. It is substantially equivalent to these other devices in design, function, material and intended use.