June 26, 2018

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

Re: K181119
Trade/Device Name: Range (Denali and Mesa) Spinal Systems
Regulation Number: 21 CFR 888.3070
Regulation Name: Thoracolumbosacral pedicle screw system
Regulatory Class: Class II
Product Code: NKB, KWQ, KWP
Dated: April 26, 2018
Received: April 27, 2018

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.

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,

Ronald P. Jean -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)*

K181119

Device Name
Range (Denali and Mesa) Spinal Systems

Indications for Use *(Describe)*

The MESA and DENALI Spinal Systems (including ARI Staples) and the EVEREST Spinal System are cleared for the following indications:

Posterior 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; pseudoarthosis; 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 MESA, DENALI and EVEREST Spinal Systems are indicated as an adjunct to fusion to treat adolescent idiopathic scoliosis when used for posterior non-cervical fixation in pediatric patients. The MESA, DENALI and EVEREST 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.

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
Range (Denali and Mesa) Spinal Systems
K2M, Inc.

Submitter

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

Contact Person: Nancy Giezen
Telephone: 571 919-2168
Date Prepared: 06/26/2018

Classification

Trade Name:	Range (Denali and Mesa) Spinal Systems
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 and Mesa) Spinal Systems (K171832)

Additional Predicates:
K2M EVEREST Spinal System (K173508)

Device Description

The Range (Denali and Mesa) Spinal Systems are top-loading, multiple component, posterior (thoracic-lumbar) spinal fixation systems consisting of pedicle screws, rods, hooks and rod connectors. The purpose of this 510(k) is to add revision connectors and rods to the system.

Function: The systems function as spinal fixation devices to provide support and stabilization of the posterior thoracic and lumbar spine.

Indications For Use

The MESA and DENALI Spinal Systems (including ARI Staples) and the EVEREST Spinal System are cleared for the following indications:

Posterior 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; pseudoarthosis; 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 MESA, DENALI and EVEREST Spinal Systems are indicated as an adjunct to fusion to treat adolescent idiopathic scoliosis when used for posterior non-cervical fixation in pediatric patients. The MESA, DENALI and EVEREST 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 and Mesa) Spinal Systems were 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 and Mesa) Systems 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.