October 5, 2018

K2M Inc.
% Karen E. Warden, Ph.D.
President
BackRoads Consulting, Inc.
P.O. Box 566
Chesterland, Ohio 44026

Re: K181603
Trade/Device Name: EVEREST Spinal System, RANGE (MESA and DENALI) Spinal System, CASPIAN OCT (MESA Mini and DENALI Mini) Spinal System, YUKON OCT Spinal System
Regulatory Class: Unclassified
Product Code: NKG, NKB, KWP, KWQ
Dated: June 18, 2018
Received: June 19, 2018

Dear Dr. Warden:

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,

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)*

K181603

Device Name
EVEREST Spinal System

Indications for Use *(Describe)*

The EVEREST Spinal System may be used in conjunction with the RANGE® (MESA® and DENALI®) Spinal Systems, all of which 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; pseudarthrosis; and/or failed previous fusion.

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

When used for posterior non-cervical pedicle screw fixation in pediatric patients the EVEREST Spinal System implants are indicated as an adjunct to fusion to treat adolescent idiopathic scoliosis. These devices are 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

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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)*

K181603

Device Name

RANGE (MESA and DENALI) Spinal System

Indications for Use *(Describe)*

Range (Mesa and Denali) and ARI 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; 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 noncervical 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

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)

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510(k) Number *(if known)*

K181603

Device Name

Caspian OCT (MESA Mini and DENALI Mini) Spinal System

Indications for Use *(Describe)*

The Caspian OCT/MESA Mini/DENALI Mini Spinal System is intended to provide immobilization and stabilization of spinal segments as an adjunct to fusion for the following acute and chronic instabilities of the craniocervical junction, the cervical spine (C1 to C7) and the thoracic spine (T1-T3): traumatic spinal fractures and/or traumatic dislocations; instability or deformity; failed previous fusions (e.g., pseudoarthrosis); tumors involving the cervical spine; and degenerative disease, including intractable radiculopathy and/or myelopathy, neck and/or arm pain of discogenic origin as confirmed by radiographic studies, and degenerative disease of the facets with instability.

The Caspian OCT/MESA Mini/DENALI Mini Spinal System is also intended to restore the integrity of the spinal column even in the absence of fusion for a limited time period in patients with advanced stage tumors involving the cervical spine in whom life expectancy is of insufficient duration to permit achievement of fusion.

In order to achieve additional levels of fixation, the Caspian OCT/MESA Mini/DENALI Mini Spinal System may be connected to Range/MESA/DENALI Spinal System and Everest Spinal System components via the rod to rod connectors or transition rods.

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)

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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)*
K181603

Device Name
YUKON OCT Spinal System

Indications for Use *(Describe)*

The YUKON OCT Spinal System is intended to provide immobilization and stabilization of spinal segments as an adjunct to fusion for the following acute and chronic instabilities of the craniocervical junction, the cervical spine (C1to C7) and the thoracic spine (T1-T3): traumatic spinal fractures and/or traumatic dislocations; instability or deformity; failed previous fusions (e.g., pseudoarthrosis); tumors involving the cervical spine; and degenerative disease, including intractable radiculopathy and/or myelopathy, neck and/or arm pain of discogenic origin as confirmed by radiographic studies, and degenerative disease of the facets with instability.
The YUKON OCT Spinal System is also intended to restore the integrity of the spinal column even in the absence of fusion for a limited time period in patients with advanced stage tumors involving the cervical spine in whom life expectancy is of insufficient duration to permit achievement of fusion.

In order to achieve additional levels of fixation, the YUKON OCT Spinal System may be connected to Everest Spinal System components via the rod to rod connectors or transition rods

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)

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510(k) Summary

Date:	18 June 2018
Sponsor:	K2M Inc. 600 Hope Pkwy. SE Leesburg, Virginia 20175 Phone: 571.919.2000
Sponsor Contact:	Nancy Giezen
510(k) Contact:	Karen E. Warden, PhD BackRoads Consulting PO Box 566 Chesterland, OH 44026 Office: 440.729.8457
Trade Names:	EVEREST, RANGE (MESA and DENALI), CASPIAN OCT (MESA Mini and DENALI Mini) and YUKON OCT Spinal Systems
Common Name:	Spinal Fixation Systems
Regulatory Class:	Class II
Classification Names, Regulations, Product Codes:	Appliance, fixation, spinal interlaminal, 888.3050, KWP Appliance, fixation, spinal intervertebral body, 888.3060, KWQ Thoracolumbosacral pedicle screw system, 888.3070, NKB Orthosis, cervical pedicle screw spinal fixation, unclassified, NKG
Device Description:	The previously cleared K2M EVEREST, RANGE (MESA and DENALI), CASPIAN OCT (MESA Mini and DENALI mini) and YUKON OCT Spinal Systems are top-loading, multiple component posterior spinal fixation implants consisting of pedicle screws, hooks, rods and connectors, intended to provide support during spinal fusion procedures. The primary purpose of this submission is to establish an MR Conditional labeling claim for these implants. In addition, CASPIAN components that were previously provided non-sterile are now being optionally offered as sterile packaged devices.
Indications for Use:	EVEREST® Spinal System: The EVEREST® Spinal System may be used in conjunction with the RANGE® (MESA® and DENALI®) Spinal Systems, all of which 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; pseudarthrosis; and/or failed previous fusion. Except for hooks, when used as an anterolateral thoracic/lumbar system the EVEREST® Spinal System may also be used for the same indications as an adjunct to fusion. When used for posterior non-cervical pedicle screw fixation in pediatric patients the EVEREST® Spinal System implants are indicated as an adjunct to fusion to treat adolescent idiopathic scoliosis. These devices are to be used with autograft and/or allograft. Pediatric pedicle screw fixation is limited to a posterior approach.
	RANGE® (MESA® and DENALI®) Spinal System: Range (Mesa and Denali) and ARI 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; 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 noncervical 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
	CASPIAN OCT (MESA Mini and DENALI mini) Spinal System: The Caspian OCT/MESA Mini/DENALI Mini Spinal System is intended to provide immobilization and stabilization of spinal segments as an adjunct to fusion for the following acute and chronic instabilities of the craniocervical junction, the cervical spine (C1 to C7) and the thoracic spine (T1-T3): traumatic spinal fractures and/or traumatic dislocations; instability or deformity; failed previous fusions (e.g., pseudoarthrosis); tumors involving the cervical spine; and degenerative disease, including intractable radiculopathy and/or myelopathy, neck and/or arm pain of discogenic origin as confirmed by radiographic studies, and degenerative disease of the facets with instability. The Caspian OCT/MESA Mini/DENALI Mini Spinal System is also intended to restore the integrity of the spinal column even in the absence of fusion for a limited time period in patients with advanced stage tumors involving the cervical spine in whom life expectancy is of insufficient duration to permit achievement of fusion. In order to achieve additional levels of fixation, the Caspian OCT/MESA Mini/DENALI Mini Spinal System may be connected to Range/MESA/DENALI Spinal System and Everest Spinal System components via the rod to rod connectors or transition rods.
	YUKON OCT Spinal System: The YUKON OCT Spinal System is intended to provide immobilization and stabilization of spinal segments as an adjunct to fusion for the following acute and chronic instabilities of the craniocervical junction, the cervical spine (C1to C7) and the thoracic spine (T1-T3): traumatic spinal fractures and/or traumatic dislocations; instability or deformity; failed previous fusions (e.g., pseudoarthrosis); tumors involving the cervical spine; and degenerative disease, including intractable radiculopathy and/or myelopathy, neck and/or arm pain of discogenic origin as confirmed by radiographic studies, and degenerative disease of the facets with instability. The YUKON OCT Spinal System is also intended to restore the integrity of the spinal column even in the absence of fusion for a limited time period in patients with advanced stage tumors involving the cervical spine in whom life expectancy is of insufficient duration to permit achievement of fusion. In order to achieve additional levels of fixation, the YUKON OCT Spinal System may be connected to Everest Spinal System components via the rod to rod connectors or transition rods.
Materials:	The EVEREST, RANGE (MESA and DENALI), CASPIAN OCT (MESA Mini and DENALI Mini) and YUKON OCT Spinal Systems are manufactured from titanium alloy (ASTM F136 and ASTM F1472), titanium (ASTM F67) and cobalt chrome (ASTM F1537). The materials used in the manufacturing of the instruments are stainless steel with some of the instruments

	incorporating aluminum, linen phenolic, Ultem, Radel, polypropelene, acetal copolymer, or silicone in the handles or retractor blades
Primary Predicate:	EVEREST Spinal System (K2M Inc. – K181188)
Additional Predicates:	RANGE (MESA and DENALI) Spinal System (K2M Inc. – K171832), CASPIAN OCT (MESA Mini and DENALI Mini) Spinal System (K2M Inc. – K153370), YUKON OCT Spinal System (K2M Inc. – K171444)
Reference Devices:	Vertex™ Reconstruction System (Medtronic Sofamor Danek USA , Inc. – K180851), Magec® System (NuVasive Specialized Orthopedics– K171791)
Performance Data:	MR Compatibility testing per ASTM F2503 was performed. The test results demonstrate that the EVEREST, RANGE (MESA and DENALI), CASPIAN OCT (MESA Mini and DENALI Mini) and YUKON OCT Spinal Systems performance is substantially equivalent to the predicate devices.
Technological Characteristics:	The EVEREST, RANGE (MESA and DENALI), CASPIAN OCT (MESA Mini and DENALI Mini) and YUKON OCT Spinal Systems possess the same technological characteristics as their predicate devices; no changes have been made to any of the devices. Therefore the fundamental scientific technology of the EVEREST, RANGE (MESA and DENALI), CASPIAN OCT (MESA Mini and DENALI Mini) and YUKON OCT Spinal Systems is the same as previously cleared devices.
Conclusion:	The EVEREST, RANGE (MESA and DENALI), CASPIAN OCT (MESA Mini and DENALI Mini) and YUKON OCT Spinal Systems possess the same intended use and technological characteristics as the predicate devices. Therefore the EVEREST, RANGE (MESA and DENALI), CASPIAN OCT (MESA Mini and DENALI Mini) and YUKON OCT Spinal Systems are substantially equivalent.