DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

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

August 8, 2017

Re: K171444
Trade/Device Name: YUKON OCT Spinal System
Regulatory Class: Unclassified
Product Code: NKG, KWP
Dated: May 15, 2017
Received: May 16, 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)*

K171444

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 (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 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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) SUMMARY
YUKON OCT Spinal System

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

Contact Person: Nancy Giezen
Telephone: 571-919-2000
Date Prepared: 7/19/2017

Classification

Trade Name:	YUKON OCT Spinal System
Common Name:	Spinal Fixation System
Regulatory Class:	Unclassified (NKG), Class II (KWP)

Classification Name(s):
Orthosis, cervical pedicle screw spinal fixation (Unclassified, Product Code NKG)
Appliance, fixation, spinal interlaminal (21 CFR 888.3050, Product Code KWP)

Predicate Device(s)
Primary Predicate:
K2M Caspian OCT/MESA Mini/DENALI Mini Spinal System (081107)

Additional Predicates:
K2M Caspian OCT/MESA Mini/DENALI Mini Spinal System (K101084, K153370)
DePuy Mountaineer (K042508, K110353)
Zimmer Virage (K133556)
Biomet Lineum (K151224)
Synthes Synapse (K142838)
Occipital Rod/Plate, CerviFix (K982322, K984377)
Medtronic Vertex (K052402, K083071)

Reference Devices:
K2M Everest Spinal System (K161369)
K2M Range/Mesa/Denali (K141147)

Device Description
The YUKON OCT Spinal System is a top-loading, multiple component, posterior (occipital-cervical-thoracic) spinal fixation system consisting of screws, hooks, rods, rod connectors, and occipital components.

Function: The system functions as an adjunct to fusion to provide stabilization of the posterior cervical and thoracic spine.

Indications for Use

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 (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 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.

Technological Comparison to Predicate(s)

The subject implants were compared to predicate systems and the design features, materials and sizes were found to be substantially the same as these systems. The method of attachment to the posterior spine is also the same as the predicate devices. However each of the YUKON implants are designed to attach to multiple rod sizes (similar to the K2M EVEREST Spinal System). Pedicle screws, hooks and transverse connectors attach to 3.5mm or 4.0mm diameter rods while the 3.5mm/4.0mm rod to rod connectors can link to rod diameters of 5.5mm or 6.0mm.

Non-clinical Performance Evaluation

Published literature and mechanical testing per ASTM F1717 and F2706 (static torsion, static compression, dynamic torsion, dynamic compression) revealed that the YUKON OCT Spinal System is substantially equivalent to the predicate devices.

Conclusion

There are no significant differences between the YUKON OCT Spinal 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.