DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

August 10, 2015

K2M, Incorporated
Ms. Nancy Giezen
Manager Regulatory Affairs
751 Miller Drive Southeast
Leesburg, Virginia 20175

Re: K151216
Trade/Device Name: Everest Spinal System
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle screw spinal system
Regulatory Class: Class III
Product Code: NKB, OSH, MNH, MNI, KWQ, KWP
Dated: July 10, 2015
Received: July 13, 2015

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" (21CFR 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 yours,

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)*
K151216

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.

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510(k) Summary
Everest Spinal System

Submitter :
K2M, Inc.
751 Miller Drive SE
Leesburg, VA 20175

Contact Person: Nancy Giezen
Telephone: 571 919 2000
Date Prepared: 7/29/2015

Classification

Tradename:	Everest Spinal System
Common Name:	Spinal Fixation System
Regulatory Class:	Class II, Class III (NKB)

Classification Name(s):
Pedicle Screw Spinal System (21 CFR 888.3070, Product Codes NKB, OSH, MNH, MNI)
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 Predicate
Everest Spinal System (K142360)
Additional Predicates

- Everest Spinal System (K103440)
- Medtronic CD Horizon (K140449)
- Stryker Xia (K142381)

Device Description

The Everest Spinal System is a top-loading, multiple component, posterior (thoracic-lumbar) spinal fixation system which consists of pedicle screws, rods, hooks and rod connectors. The Everest Spinal System implants are manufactured from titanium alloy per ASTM F136 and F1472 and Cobalt Chrome per ASTM F1537. The subject 510(k) adds additional connectors and rods to the system.

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

Indications for Use

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.

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Technological Comparison to Predicate(s)
The proposed Everest implants 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 was conducted in accordance with ASTM F1717 (including static torsion, static compression, and dynamic compression bending) and the results were comparable to previously cleared devices.

Conclusion:
There are no significant differences between the Everest Spinal System and other devices currently being marketed which would adversely affect the use of the product. In addition, the data demonstrate substantial equivalence of the subject device to predicate devices. Therefore the subject devices are substantially equivalent to the predicate devices.