510(k) Summary
for the
Range (Mesa/Denali) and Everest Spinal Systems

This 510(k) summary for the Range Spinal System is provided as required per Section 513(i)(3) of the Food, Drug and Cosmetic Act.

1. Submitter :
K2M, Inc.
751 Miller Drive SE,
Suite F1
Leesburg, VA 20175

Contact Person :
Nancy Giezen
K2M, Inc.
Telephone: 703-777-3155

Date Prepared: 03/20/14

2. Tradename:	Range Spinal System, Everest Spinal System
Common Name:	Spinal Fixation System
Classification Name:	Pedicle Screw Spinal System (21CFR 888.3070) Spinal Interlaminal Fixation Orthosis (21CFR 888.3050) Orthosis, Spondylolisthesis Spinal Fixation (21CFR 888.3070)
Device Product Code:	MNH, MNI, KWP, OSH, NKB
Regulatory Class:	Class III

3. Predicate or legally marketed devices which are substantially equivalent :

- Medtronic CD Horizon K032033, K091445
- K2M Range Spinal System K070229, K121639, KK122877, K123412, K130330, K131030, K131784
- K2M Everest Spinal System K103440, K120656, K132361, K132757

4. Description of the device:

The Range and Everest Spinal Systems are top-loading, multiple component, posterior (thoracic-lumbar) spinal fixation system which consist of pedicle screws, rods, locking set screws, hooks, rod connectors and transverse connectors.

Materials: The devices are manufactured from Titanium Alloy and Cobalt Chrome per ASTM and ISO standards.

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

The purpose of this submission is to expand the indications for use for the Range and Everest Spinal Systems

5. Intended Use:

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 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.

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: 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.

6. Comparison of the technological characteristics of the device to predicate and legally marketed devices :

The design features and sizing of the components were compared to predicate devices and the Range and Everest Spinal Systems were found to be substantially the same as these systems.

7. Comparison of the performance data of the device to predicate and legally marketed devices :

The Range and Everest Spinal System components were previously tested in static compression, static torsion and dynamic compression in accordance with ASTM F1717 and determined to be substantially equivalent to predicate devices. A review of the literature concluded that the expanded indications do not result in new issues of safety and effectiveness.

8. Conclusion:

There are no significant differences between the Range and Everest Spinal Systems and other systems currently being marketed which would adversely affect the use of the product. They are substantially equivalent to these other devices in design, function, material and intended use.

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

March 21, 2014

K2M, Incorporated
Ms. Nancy Giezen
751 Miller Drive SE, Suite F1
Leesburg, Virginia 20175

Re: K133944
Trade/Device Name: Range Spinal System, Everest Spinal System
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle screw spinal system
Regulatory Class: Class III
Product Code: NKB, OSH, MNI, MNH, KWP
Dated: December 20, 2013
Received: December 23, 2013

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 Small Manufacturers, International and Consumer Assistance 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 Small Manufacturers, International and Consumer Assistance 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,

Lori A. Wiggins

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

Enclosure

Indications for Use

510(k) Number (if known): K133944

Device Name: Everest Spinal System

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Prescription Use X AND/OR Over-the-counter Use __
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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Concurrence of Center for Devices and Radiological Health (CDRH)

Colin O'Neill

(Division Sign-Off)
Division of Orthopedic Devices
510(k) Number: K133944