JUL 3 0 2014

510(k) Summary

Date:	5 November 2013
Sponsor:	K2M Inc. 751 Miller Drive SE Leesburg, Virginia 20175 Phone: 703.777.3155
Contact Person:	Nancy Giezen
Trade Names:	RANGE (DENALI / MESA) Spinal Systems
Device Classification	Class II, Class III
Classification Names (Regulations):	Spinal Interlaminal Fixation Orthosis (888.3050) Spinal intervertebral body fixation orthosis (888.3060) Pedicle Screw Spinal System (888.3070)
Device Product Codes:	KWP, KWQ, MNI, MNH, NKB, OSH
Submission Purpose:	This submission adds the K2M Modular Hooks to the Range (Denali/Mesa) Spinal System.
Device Description:	The RANGE / DENALI / MESA Spinal Systems are top-loading, multiple component, posterior (thoracic-lumbar) spinal fixation systems which consists of pedicle screws, rods, hooks and rod connectors. The K2M Modular Hook is comprised of a hook body and a variety of adjustable blade options.
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.
Materials:	The K2M Modular Hooks components are manufactured from titanium alloy (Ti-6Al-4V ELI) as described by ASTM and ISO standards.
Predicate Devices:	K2M MESA® Spinal System (K052398/K080611) K2M Range (Mesa/Denali) Spinal System (K141147) Medtronic CD Horizon (K962708/K031655)

Performance Data:

The worst case K2M Modular Hook was evaluated using static and dynamic compression bending tests according to ASTM F1717, and static A-P and disassembly tests according to ASTM F1798.

The mechanical test results demonstrate that the K2M Modular Hook performance is substantially equivalent to the predicate MESA Spinal System performance.

Technological Characteristics:

The K2M Modular Hook components possess the same technological characteristics as the predicate devices. These include:

- basic design (rod-based hook attachment),
- material (titanium alloy),
- anatomic location (non-cervical spine) and
- sizes (widths, lengths and heights are within the range(s) offered by the predicate systems).

Technological characteristics which are different have been supported with descriptive information and/or performance data which demonstrate the safety and effectiveness has not been diminished.

Conclusion:

In comparison to the predicate devices, the K2M Modular Hooks has

- the same intended use (as described above),
- the same technological characteristics or different without raising safety and effectiveness issues (as described above)

Therefore the K2M Modular Hooks can be found substantially equivalent to the predicate devices.

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

July 30, 2014

K2M, Incorporated
% Karen E. Warden, Ph.D.
BackRoads Consulting, Incorporated
8202 Sherman Road
Chesterland, Ohio 44026

Re: K133402
Trade/Device Name: RANGE (DENALI/MESA) Spinal Systems
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle screw spinal system
Regulatory Class: Class III
Product Code: NKB, OSH, MNI, MNH, KWP, KWQ
Dated: June 26, 2014
Received: June, 27, 2014

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. 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 yours,

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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K133402

Device Name
RANGE (DENALI/MESA) Spinal Systems

Indications for Use *(Describe)*
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.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Zane W. Wyatt
Division of Orthopedic Devices

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