510(k) Summary
for the
Range Spinal System: Small Stature, Additional Components

FEB 1 3 2013

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,
Leesburg, VA 20175

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

Date Prepared: 11/05/12

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

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

- K2M Range Spinal System (K070229, K120099, K121630)

4. Description of the device:

The Range Spinal System is a top-loading, multiple component, posterior (thoracic-lumbar) spinal fixation system which consists of pedicle screws, rods, locking set screws, and hooks.

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 add modified Small Stature components (screws, hooks and connectors) to the system.

5. Intended Use:

RANGE /DENALI, MESA and SMALL STATURE and ARI are cleared for the following indications:

Non-cervical, pedicle screw fixation devices for posterior stabilization as an adjunct to fusion for the following indications: trauma (i.e. fracture or dislocation); spinal stenosis; curvatures (i.e. scoliosis, kyphosis; and/or lordosis); tumor; pseudoarthrosis; and failed previous fusion. It is also indicated for the treatment of severe spondylolisthesis (grades 3 and 4) of the L5-S1 vertebra in skeletally mature patients receiving fusion by autogenous bone graft having implants attached to the lumbar and sacral spine (L3 to sacrum) with removal of the implants after the attainment of a solid fusion.

Non-cervical, non-pedicle spinal fixation devices intended for posterior or anterolateral thoracolumbar screw stabilization as an adjunct to fusion, in skeletally mature patients, for the following indications: degenerative disc disease (DDD) (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; pseudoarthrosis; and failed previous 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.

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 Spinal System was 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 modified implants were compared with predicate devices that were previously tested in static compression, static torsion and dynamic compression in accordance with ASTM. The modified implants were determined to be substantially equivalent to the predicate devices.

8. Conclusion:

There are no significant differences between the Range 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.

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

K2M, Incorporated
% Ms. Nancy Giezen
Manager, Regulatory Affairs
751 Miller Drive SE, Suite F1
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FEB 13 2013

Re: K123412
Trade/Device Name: Range Spinal System
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle screw spinal system
Regulatory Class: Class II
Product Code: OSH, MNH, MNI, KWP
Dated: January 16, 2013
Received: January 24, 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). You may, therefore, market the device, subject to the general controls provisions of the Act and the limitations described below. 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.

The Office of Device Evaluation has determined that there is a reasonable likelihood that this device will be used for an intended use not identified in the proposed labeling and that such use could cause harm. Therefore, in accordance with Section 513(i)(1)(E) of the Act, the following limitation must appear in the Precautions/Warnings/Contraindications section of the device's labeling:

"The safety and effectiveness of this device has not been established for use as part of a growing rod construct. This device is only intended to be used when definitive fusion is being performed at all instrumented levels."

Please note that the above labeling limitations are required by Section 513(i)(1)(E) of the Act. Therefore, a new 510(k) is required before these limitations are modified in any way or removed from the device's labeling.

The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and permits your device to proceed to the market. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification if the limitation statement described above is added to your labeling.

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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,

Christy Foreman

Christy Foreman
Director
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K123412

Device Name: Range Spinal System

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

(PLEASE DO NOT WRITE BELOW THIS-LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Ronald P. Jean -S

(Division Sign-Off)
Division of Orthopedic Devices
510(k) Summary: K123412