



May 30, 2018

K2M Inc.
% Karen E. Warden, Ph.D.
President
BackRoads Consulting, Inc.
P.O. Box 566
Chesterland, Ohio 44026-0566

Re: K181188
Trade/Device Name: EVEREST Spinal System
Regulation Number: 21 CFR 888.3070
Regulation Name: Thoracolumbosacral pedicle screw system
Regulatory Class: Class II
Product Code: NKB, KWQ, KWP
Dated: May 2, 2018
Received: May 3, 2018

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.

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 comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (<https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/>) and CDRH Learn (<http://www.fda.gov/Training/CDRHLearn>). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (<http://www.fda.gov/DICE>) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Ronald P. Jean -S

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)

K181188

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)

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)

510(k) Summary

Date:	2 May 2018
Sponsor:	K2M Inc. 600 Hope Pkwy. SE Leesburg, Virginia 20175 Phone: 571.919.2000
Sponsor Contact:	Nancy Giezen
510(k) Contact:	Karen E. Warden, PhD BackRoads Consulting PO Box 566 Chesterland, OH 44026 Office: 440.729.8457
Trade Names:	EVEREST Spinal System
Common Name:	Pedicle screw system
Device Classification	Class II
Classification Name, Regulation, Product Code:	Thoracolumbosacral pedicle screw system, 888.3070, NKB Spinal intervertebral body fixation orthosis, 888.3060, KWQ Spinal interlaminar fixation orthosis, 888.3050, KWP
Submission Purpose:	The subject 510(k) adds a set screw to the EVEREST Spinal System.
Device Description:	The EVEREST Spinal System is a top-loading, multiple component, posterior (thoracic/lumbar/sacral) spinal fixation system consisting of pedicle screws, hooks, rods and connectors.
Intended 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. 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.
Primary Predicate:	EVEREST Spinal System (K2M Inc. – K161369)
Performance Data:	The modified device was evaluated via finite element analyses. The results demonstrated the performance of the modified set screw is substantially equivalent to the predicate.

**Technological
Characteristics:**

The modified EVEREST Spinal System set screw possesses technological characteristics similar to the predicate device. These include:

- performance (as described above),
- basic design (threaded fastener),
- implant grade materials (titanium alloy), and
- size (diameter and thread form) offered by the predicate).

Therefore the fundamental scientific technology of the modified EVEREST Spinal System set screw is the similar to the previously cleared device.

Conclusion:

The modified EVEREST Spinal System set screw possesses the same intended use and similar technological characteristics as the predicate device. Therefore the EVEREST Spinal System set screw is substantially equivalent to the legally marketed predicate.