



Food and Drug Administration  
10903 New Hampshire Avenue  
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K2M, Incorporated  
Ms. Nancy Giezen  
Manager, Regulatory Affairs  
751 Miller Drive Southeast  
Leesburg, Virginia 20175

February 16, 2016

Re: K153370

Trade/Device Name: Caspian OCT/MESA Mini/DENALI Mini Spinal System  
Regulatory Class: Unclassified  
Product Code: NKG, KWP  
Dated: November 20, 2015  
Received: November 23, 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" (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,

**Mark N. Melkerson -S**

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)

K153370

Device Name

Caspian OCT/MESA Mini/DENALI Mini Spinal System

### Indications for Use (Describe)

The Caspian OCT/MESA Mini/DENALI Mini Spinal System is intended to provide immobilization and stabilization of spinal segments as an adjunct to fusion for the following acute and chronic instabilities of the craniocervical junction, the cervical spine (C1 to C7) and the thoracic spine (T1-T3): traumatic spinal fractures and/or traumatic dislocations; instability or deformity; failed previous fusions (e.g., pseudoarthrosis); tumors involving the cervical spine; and degenerative disease, including intractable radiculopathy and/or myelopathy, neck and/or arm pain of discogenic origin as confirmed by radiographic studies, and degenerative disease of the facets with instability. The Caspian OCT/MESA Mini/DENALI Mini Spinal System is also intended to restore the integrity of the spinal column even in the absence of fusion for a limited time period in patients with advanced stage tumors involving the cervical spine in whom life expectancy is of insufficient duration to permit achievement of fusion. In order to achieve additional levels of fixation, the Caspian OCT/MESA Mini/DENALI Mini Spinal System may be connected to Range/MESA/DENALI Spinal System and Everest Spinal System components via the rod to rod connectors or transition rods.

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)

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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**510(k) SUMMARY**  
**Caspian OCT/MESA Mini/DENALI Mini Spinal System**

**Submitter**

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

Contact Person: Nancy Giezen  
Telephone: 703-777-3155  
Date Prepared: 2/12/2016

**Classification**

Trade Name: Caspian OCT/MESA Mini/ DENALI Mini Spinal System  
Common Name: Spinal Fixation System  
Regulatory Class: Unclassified (NKG), Class II (KWP)

## Classification Name(s):

Orthosis, cervical pedicle screw spinal fixation (Unclassified, Product Code NKG)  
Appliance, fixation, spinal interlaminar (21 CFR 888.3050, Product Code KWP)

**Predicate Device(s)**

## Primary Predicate:

Nuvasive VuePoint II OCT System (K150474)

## Additional Predicates:

K2M Caspian OCT/MESA Mini/DENALI Mini Spinal System (K081107)

K2M Caspian OCT/MESA Mini/DENALI Mini Spinal System (K133288)

Medtronic Vertex Reconstruction System (K152338)

Stryker Oasys System (K151755)

DePuy Summit SI OCT Spinal Fixation System, Mountaineer OCT Spinal System (K151885)

Globus Ellipse and Protex CT Occipitio-Cervico-Thoracic Spinal Systems (K150552)

**Device Description**

The Caspian OCT/MESA Mini/ DENALI Mini Spinal System is a top-loading, multiple component, posterior (occipital-cervical-thoracic) spinal fixation system. The purpose of the current submission is to add modified plates and rods and to revise the Indications for Use.

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

**Indications for Use**

The Caspian OCT/MESA Mini/DENALI Mini Spinal System is intended to provide immobilization and stabilization of spinal segments as an adjunct to fusion for the following acute and chronic instabilities of the craniocervical junction, the cervical spine (C1 to C7) and the thoracic spine (T1-T3): traumatic spinal fractures and/or traumatic dislocations; instability or deformity; failed previous fusions (e.g., pseudoarthrosis); tumors involving the cervical spine; and degenerative disease, including intractable radiculopathy and/or myelopathy, neck and/or arm pain of discogenic origin as confirmed by radiographic studies, and degenerative disease of the facets with instability.

The Caspian OCT/MESA Mini/DENALI Mini Spinal System is also intended to restore the integrity of the spinal column even in the absence of fusion for a limited time period in patients with advanced stage tumors involving the cervical spine in whom life expectancy is of insufficient duration to permit achievement of fusion.

In order to achieve additional levels of fixation, the Caspian OCT/MESA Mini/DENALI Mini Spinal System may be connected to Range/MESA/DENALI Spinal System and Everest Spinal System components via the rod to rod connectors or transition rods.

#### **Technological Comparison to Predicate(s)**

The proposed modifications 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**

Published literature and mechanical testing per ASTM F1717 and F2706 (static torsion, static compression, dynamic torsion, dynamic compression), and biomechanical (cadaver) testing demonstrates the Caspian OCT/MESA Mini/DENALI Mini Spinal System is substantially equivalent to the predicate devices.

#### **Conclusion**

There are no significant differences between the Caspian OCT/MESA Mini/ DENALI Mini 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.