

JUL 23 2014

510(k) Summary  
For the  
**CASPIAN OCT/MESA Mini/ DENALI Mini System**

This 510(k) summary for the CASPIAN OCT/MESA Mini/ DENALI Mini System is provided as required per Section 513(i)(3) of the Food, Drug and Cosmetic Act.

- |  |  |
|--|--|
| <b>1. Submitter:</b><br>K2M, Inc.<br>751 Miller Drive SE<br>Leesburg, VA 20175 | <b>Contact Person:</b><br>Nancy Giezen<br>K2M, Inc.<br>Telephone: 703-777-3155 |
|--|--|

Date Prepared: 07/22/2014

- |                             |   |
|-----------------------------|---|
| <b>2. Tradename:</b>        | CASPIAN OCT/MESA Mini/ DENALI Mini System               |
| <b>Common Name:</b>         | Spinal Fixation System                                  |
| <b>Classification Name:</b> | Spinal Interlaminar Fixation Orthosis (21 CFR 888.3050) |
| <b>Device Product Code:</b> | KWP   |
| <b>Regulatory Class:</b>    | Class II  |

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

- K2M Caspian Spinal System (K081107)
- K2M Caspian OCT Spinal System (K101084)
- Biomet Altius System (K033961, K043229, K122378)

**4. Description of the device:**

The CASPIAN OCT/MESA Mini/ DENALI Mini System is a top-loading, multiple component, posterior (occipital-cervical-thoracic) spinal fixation system. The purpose of the current submission is to add Ø3.5 contoured rods to expand the rod offerings for the system.

**Materials:** The subject devices are manufactured from Ti6Al4V Eli per ASTM and ISO standards.

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

**5. Intended Use:**

The CASPIAN OCT/MESA Mini/ DENALI Mini Spinal System is intended to provide stabilization as an adjunct to fusion of the cervical spine and occipito-cervico-thoracic junction (occiput-T3) when used with autograft or allograft and indicated for the following:

- DDD (neck pain of discogenic origin with degeneration of the disc as confirmed by patient history and radiographic studies)

- Spondylolisthesis
- Spinal stenosis
- Fracture/dislocation
- Revision of previous cervical spine surgery
- Tumors
- Atlantoaxial fracture with instability
- Occipitocervical dislocation

The occipital bone screws are limited to occipital fixation only

The rod and hook components are intended for use in the cervical/upper thoracic (C1-T3) spine. The pedicle screws are limited to placement in the T1-T3 in treating thoracic conditions only. The pedicle screws are not intended to be placed in or treat conditions involving the cervical spine.

The CASPIAN OCT/MESA Mini/ DENALI Mini System can also be linked to the Range Spinal System using rod connectors or transitional rods.

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

The worst case components of the CASPIAN OCT/MESA Mini/ DENALI Mini System were previously tested in accordance with ASTM F1717 and determined to be equivalent to predicate devices. The subject rods were determined not to represent a new worst case via finite element analysis and engineering rationale. There are no significant differences between the CASPIAN OCT/MESA Mini/ DENALI Mini 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.



Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Center – WO66-G609  
Silver Spring, MD 20993-0002

July 23, 2014

K2M, Incorporated  
Ms. Nancy Giezen  
Manager, Regulatory Affairs  
751 Miller Drive Southeast  
Leesburg, Virginia 20175

Re: K141284

Trade/Device Name: CASPIAN OCT/MESA Mini/DENALI Mini Spinal System  
Regulation Number: 21 CFR 888.3050  
Regulation Name: Spinal interlaminar fixation orthosis  
Regulatory Class: Class II  
Product Code: KWP  
Dated: June 23, 2014  
Received: June 24, 2014

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

Page 2 – Ms. Nancy Giezen

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

**Indications for Use**

510(k) Number (if known)  
K141284

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 stabilization as an adjunct to fusion of the cervical spine and occipito-cervico-thoracic junction (occiput-T3) when used with autograft or allograft and indicated for the following:

- DDD (neck pain of discogenic origin with degeneration of the disc as confirmed by patient history and radiographic studies)
- Spondylolisthesis
- Spinal stenosis
- Fracture/dislocation
- Revision of previous cervical spine surgery
- Tumors
- Atlantoaxial fracture with instability
- Occipitocervical dislocation

The occipital bone screws are limited to occipital fixation only

The rod and hook components are intended for use in the cervical/upper thoracic (C1-T3) spine. The pedicle screws are limited to placement in the T1-T3 in treating thoracic conditions only. The pedicle screws are not intended to be placed in or treat conditions involving the cervical spine.

The CASPIAN OCT/MESA Mini/ DENALI Mini System can also be linked to the Range Spinal System using rod connectors or transitional 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)

**Jonathan H. Peck -S**

---

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

**\*DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.\***

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services  
Food and Drug Administration  
Office of Chief Information Officer  
Paperwork Reduction Act (PRA) Staff  
[PRASStaff@fda.hhs.gov](mailto:PRASStaff@fda.hhs.gov)

*\*An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number.\**