



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

December 21, 2015

Re: K151481
Trade/Device Name: SAHARA Stabilization System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: OVD
Dated: November 16, 2015
Received: November 17, 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 Parts 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" (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 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)

K151481

Device Name

Sahara Stabilization System

Indications for Use (Describe)

The SAHARA Stabilization System implants are indicated for spinal fusion procedures to be used with autogenous bone graft in skeletally mature patients. Lumbar implants are intended for use at either one level or two contiguous levels in the lumbar spine, from L2 to S1, for the treatment of degenerative disc disease (DDD) with up to Grade 1 spondylolisthesis or retrolisthesis. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The lumbar device is intended to be used in patients who have had six months of non-operative treatment.

The hyperlordotic lumbar implants (at angles $> 15^\circ$) must be used with supplemental fixation (i.e., posterior pedicle screw and rod system) cleared for use in the lumbar spine, in addition to the bone screws provided. Otherwise, the Sahara Stabilization System implants may be used as a stand-alone device, which is intended to be used with the bone screws provided.

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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary
Sahara Stabilization System
K2M, Inc.

Submitter

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

Contact Person: Nancy Giezen
Telephone: (571) 919-2000
Date Prepared: 12/16/2015

Classification

Trade Name: Sahara Stabilization System
Common Name: Spinal Fixation System
Regulatory Class: Class II

Classification Name(s):

Intervertebral Body Fusion Device with Integrated Fusion (21 CFR 888.3080, Product Code OVD)

Predicate Device(s)

Primary Predicate:

K2M Chesapeake (K092211)

Additional Predicates:

K2M Chesapeake (K120031, 142487)

K2M Santorini (K111294)

Globus Rise (K113447)

Wenzel Spine Vari-Lift-L (K100820)

Device Description

The subject of this 510(k) submission is the Sahara Stabilization System. The implants function as an expandable intervertebral body fusion devices to provide support and stabilization to the lumbar segments of the spine. The implants are manufactured from Titanium (ASTM F1472, F67) and Cobalt Chrome (ASTM F1537).

Indications for Use

The SAHARA Stabilization System implants are indicated for spinal fusion procedures to be used with autogenous bone graft in skeletally mature patients. Lumbar implants are intended for use at either one level or two contiguous levels in the lumbar spine, from L2 to S1, for the treatment of degenerative disc disease (DDD) with up to Grade 1 spondylolisthesis or retrolisthesis. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The lumbar device is intended to be used in patients who have had six months of non-operative treatment.

The hyperlordotic lumbar implants (at angles $> 15^\circ$) must be used with supplemental fixation (i.e., posterior pedicle screw and rod system) cleared for use in the lumbar spine, in addition to the bone screws provided. Otherwise, the Sahara Stabilization System implants may be used as a stand-alone device, which is intended to be used with the bone screws provided.

Technological Comparison to Predicate(s)

The Sahara Stabilization System was compared to predicate systems and were found to be substantially the same as these systems.

Non-clinical Performance Evaluation

Mechanical testing (including static compression, static torsion, static compression shear, dynamic compression, dynamic compression, expulsion, and subsidence) and a cadaver implantation study was performed in support of this submission and the proposed implants were determined to be substantially equivalent to predicate devices in design, function, intended use, materials, and size.

Conclusion

It is substantially equivalent to these other devices in design, function, material and intended use.