JUN 10 2014

510(k) Summary
Chesapeake Spinal Stabilization System
K2M, Inc.

This 510(k) summary for the Chesapeake Spinal Stabilization System System is provided as required per 21 CFR 807.92

1. Submitter :
K2M, Inc.
751 Miller Drive SE
Suite F1
Leesburg, VA 20175

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

Date Prepared: June 9, 2014

2. Tradename: Chesapeake Spinal System

Common Name: Intervertebral Body Fusion Device

Classification Name: Intervertebral Body Fusion Device with Integrated Fusion Cervical (Product Code OVE)
Intervertebral Fusion Device with Integrated Fusion Lumbar (Product Code: OVD)

Regulation Number: 888.3080

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

- K2M Chesapeake Spinal Stabilization System (K092211, K111439, K120031)
- Medtronic PEEK Prevail (K073285)
- Centinal Stalif-C (K072415)
- SpineSmith IN-C2 (K122630)

4. Description of the device:

The Chesapeake Spinal System consists of PEEK and titanium spacers and titanium bone screws for intervertebral body fusion, without the need for supplementary fixation. The spacers are hollow tube structures that can be packed with bone graft and allow for passage of screws for fixation to the vertebral body. Multiple sizes of implants are available to accommodate anatomical variations.

Materials: The spacers are manufactured from Medical Grade PEEK (Polyetheretherketone) OPTIMA® LT1 (Invibio™) per ISO 10993-1 USP Class VI, and ASTM F2026 and CP titanium per ASTM F67. Tantalum beads /rods to be Grade UNS R05200, UNS R05400 according to ASTM F560. The screws are fabricated from Ti6Al4V per ASTM 1472.

Function: The Chesapeake intervertebral body fusion devices are designed to provide support and stabilization of the cervical and lumbar segments of the spine.

The purpose of this 510(k) submission is to add offset cervical implants to the system.

5. Intended Use:

When used as a cervical intervertebral body fusion device, the Chesapeake implants are indicated for spinal fusion procedures to be used with autogenous bone graft in skeletally mature patients. Cervical IBF implants are intended for use at one level in the cervical spine, from C2 to T1, for the treatment of cervical disc disease (defined as neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies). The cervical device is intended to be used in patients who have had six weeks of non-operative treatment.

When used as a lumbar intervertebral body fusion device, the Chesapeake 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. 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 Chesapeake Spinal System may be used as a stand-alone device or in conjunction with supplemental fixation. When used as a stand-alone device the Chesapeake spacers are intended to be used with the bone screws provided. When using a 2 screw implant, 2 screws must be used. When using a 3 screw implant 3 screws must be used.

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

The subject implants were tested in static compression, dynamic compression, static torsion, dynamic torsion, subsidence, and expulsion in accordance with ASTM 2077 and were determined to be substantially equivalent to predicate devices.

There are no significant differences between the Chesapeake 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

June 10, 2014

K2M, Incorporated
Ms. Nancy Giezen
Manager, Regulatory Affairs
751 Miller Drive SE, Suite F1
Leesburg, Virginia 20175

Re: K133494
Trade/Device Name: Chesapeake Spinal System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: OVD, OVE
Dated: March 17, 2014
Received: March 19, 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 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

510(k) Number (if known): K133494

Device Name : **Chesapeake Spinal System**

Indications For Use :

When used as a cervical intervertebral body fusion device, the Chesapeake implants are indicated for spinal fusion procedures to be used with autogenous bone graft in skeletally mature patients. Cervical IBF implants are intended for use at one level in the cervical spine, from C2 to T1, for the treatment of cervical disc disease (defined as neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies). The cervical device is intended to be used in patients who have had six weeks of non-operative treatment.

When used as a lumbar intervertebral body fusion device, the Chesapeake implants are indicated for spinal fusion procedures to be used with autogenous bone graft in skeletally mature patients. Lumbar I 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. 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 Chesapeake Spinal System may be used as a stand-alone device or in conjunction with supplemental fixation. When used as a stand-alone device the Chesapeake spacers are intended to be used with the bone screws provided. When using a 2 screw implant, 2 screws must be used. When using a 3 screw implant 3 screws must be used.

Prescription use __X__ OR Over-the-counter use _____
(PER 21 CFR 801.109)

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

Concurrence of Center for Devices and Radiological Health (CDRH)

Anton E. Dmitriev, PhD

Division of Orthopedic Devices