DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

April 5, 2017

K2M, Inc.
Ms. Nancy Giezen
Manager, Regulatory Affairs
600 Hope Parkway Southeast
Leesburg, Virginia 20175

Re: K161332
Trade/Device Name: NILE Proximal Fixation Spinal System
Regulation Number: 21 CFR 888.3010
Regulation Name: Bone fixation cerclage
Regulatory Class: Class II
Product Code: OWI
Dated: March 6, 2017
Received: March 7, 2017

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K161332

Device Name
NILE Proximal Fixation Spinal System

Indications for Use *(Describe)*

The NILE Alternative Fixation and NILE Proximal Fixation Spinal Systems are temporary implants for use in orthopedic surgery. The systems are intended to provide temporary stabilization as a bone anchor during the development of solid bony fusion and aid in the repair of bone fractures.

The indications for use include the following applications:

1. Spinal trauma surgery, used in sublaminar, interspinous, or facet wiring techniques;
2. Spinal reconstructive surgery, incorporated into constructs for the purpose of correction of spinal deformities such as idiopathic and neuromuscular scoliosis in patients 8 years of age and older, adult scoliosis, kyphosis, and spondylolisthesis;
3. Spinal degenerative surgery, as an adjunct to spinal fusions.

The NILE Alternative Fixation and NILE Proximal Fixation Spinal Systems may also be used in conjunction with other medical implants made of similar metals whenever 'wiring' may help secure the attachment of other implants.

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
NILE Proximal Fixation Spinal System

Submitter

K2M, Inc.
600 Hope Parkway SE
Leesburg, VA 20175

Contact Person: Nancy Giezen
Telephone: 571-919-2000
Date Prepared: 4/3/2017

Classification

Trade Name: NILE Proximal Fixation Spinal System
Common Name: Bone Fixation Cerclage
Regulatory Class: Class II

Classification Name(s):
Bone Fixation Cerclage (21 CFR 888.3010, Product Code OWI)

Predicate Device(s)

Primary Predicate:
K2M NILE Alternative Fixation Spinal System (K143350)
Reference Devices:
K2M Range/ Denali/ Mesa Spinal System (K153031)
K2M Everest Spinal System (K151727)

Device Description

The NILE Proximal Fixation Spinal System is a multiple component spinal fixation system intended for application to the thoracic, lumbar and sacral spine. The band is manufactured from polyethylene terephthalate (PET) and the connectors are made from titanium alloy in accordance with ASTM F136.

Function: The NILE Proximal Fixation Spinal System is designed to be used in conjunction with spinal rod constructs for attachment to the posterior vertebral structures.

The purpose of this submission is to add bands and connectors to the Nile system.

Indications For Use

The NILE Alternative Fixation and NILE Proximal Fixation Spinal Systems are temporary implants for use in orthopedic surgery. The systems are intended to provide temporary stabilization as a bone anchor during the development of solid bony fusion and aid in the repair of bone fractures.

The indications for use include the following applications:

1. Spinal trauma surgery, used in sublaminar, interspinous, or facet wiring techniques;

2. Spinal reconstructive surgery, incorporated into constructs for the purpose of correction of spinal deformities such as idiopathic and neuromuscular scoliosis in patients 8 years of age and older, adult scoliosis, kyphosis, and spondylolisthesis;

3. Spinal degenerative surgery, as an adjunct to spinal fusions.

The NILE Alternative Fixation and NILE Proximal Fixation Spinal Systems may also be used in conjunction with other medical implants made of similar metals whenever 'wiring' may help secure the attachment of other implants.

Technological Comparison to Predicate(s)
The NILE Proximal Fixation Spinal System implants were compared to predicate devices and the design features, materials and intended uses were found to be substantially equivalent to these systems.

Non-clinical Performance Evaluation
The NILE Proximal Fixation Spinal System implants were tested in accordance with ASTM F1717 and compared to predicate devices. The NILE Proximal Fixation system implants performed equally to or better than these systems in static and dynamic compression, static torsion, static and dynamic tension and axial slip per ASTM F1798. Bacterial endotoxin testing (BET) as specified in ANSI/AAMI ST72:2011 was also performed and will be routinely repeated to ensure that the Endotoxin limit of <20EU/Device is maintained.

Conclusion
There are no significant differences between the NILE Proximal Fixation Spinal System implants 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 performance.