July 29, 2022

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

Re: K161028
Trade/Device Name: K2M Growing Spine System
Regulation Number: 21 CFR 888.3070
Regulation Name: Thoracolumbosacral pedicle screw system
Regulatory Class: Class II
Product Code: PGM

Dear Ms. Giezen:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change related to your previous substantial equivalence (SE) determination letter dated July 22, 2016. Specifically, FDA is updating this SE Letter because FDA has better categorized your device technology under regulation number, 21 CFR 888.3070.

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact Ronald Jean, OHT6: Office of Orthopedic Devices, (301)796-5650, Ronald.Jean@fda.hhs.gov.

Sincerely,

Ronald P. Jean -S

Ronald P. Jean, Ph.D.
Director
DHT6B: Division of Spinal Devices
OHT6: Office of Orthopedic Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

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

July 22, 2016

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

Re: K161028
Trade/Device Name: K2M Growing Spine System
Regulatory Class: Unclassified
Product Code: PGM
Dated: June 30, 2016
Received: July 1, 2016

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" (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,

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)*
K161028

Device Name
K2M Growing Spine System

Indications for Use *(Describe)*
The K2M Growing Spine System implants are indicated in patients with potential for additional spinal growth under 10 years of age who require surgical treatment to obtain and maintain correction of severe, progressive, life threatening, early-onset spinal deformities associated with thoracic insufficiency, including early-onset scoliosis. The Growth Guidance implants may be used with any cleared K2M rod construct ranging in diameter 4.5mm to 6.35mm. The Growth Rod Conversion implants may be used with 4.5mm and 5.5mm rod constructs. The K2M Growing Spine System is not intended to be used in conjunction with staples.

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.**

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
*PRAStaff@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."*

# 510(k) SUMMARY
# K2M, Inc.
# K2M Growing Spine System

**Submitter**

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

Contact Person: Nancy Giezen
Telephone: 571 919-2000
Date Prepared: 06/29/2016

**Classification**

| | |
|---|---|
| Trade Name: | K2M Growing Spine System |
| Common Name: | Growing Rod System |
| Regulatory Class: | Unclassified (PGM) |

Classification Name(s):
Growing Rod System (Unclassified, Product Code PGM)

**Predicate Device(s)**

Primary Predicates:
Medtronic CD HORIZON® Growth Rod Conversion Set (K133904)

Additional Predicates:
Medtronic SHILLA Growth Guidance System (K140750)
K2M Range/Denali/Mesa Spinal System (K070229, K120099, K121630, K141873)
DePuy ISOLA® and EXPEDIUM® Growing Spine Systems (K141509)
Stryker Xia® Growth Rod Conversion Set (K142114)
Orthopedic Equipment Company (K781443, K781448, K781449)

**Device Description**

The K2M Growing Spine System consists of screw and connector components. The purpose of this 510(k) is to enable these system components to be used as part of a growing rod construct.

Function: When used as part of a growing rod construct, the system implants are designed to accommodate growth in patients under 10 years of age.

**Indications For Use**

The K2M Growing Spine System implants are indicated in patients with potential for additional spinal growth under 10 years of age who require surgical treatment to obtain and maintain correction of severe, progressive, life threatening, early-onset spinal deformities associated with thoracic insufficiency, including early-onset scoliosis. The Growth Guidance implants may be

used with any cleared K2M rod construct ranging in diameter 4.5mm to 6.35mm. The Growth Rod Conversion implants may be used with 4.5mm and 5.5mm rod constructs. The K2M Growing Spine System is not intended to be used in conjunction with staples.

**Technological Comparison to Predicate(s)**
The K2M Growing Spine System was 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**
Performance evaluations were previously conducted on constructs representing the worst case components (including static torsion, static compression and dynamic compression bending in accordance with ASTM F1717). In the current submission, engineering rationales determined that the proposed implants were substantially equivalent to the predicate devices. Bacterial endotoxin testing was also conducted in support of substantial equivalence.

**Conclusion**
There are no significant differences between the K2M Growing Spine 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.