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

January 5, 2016

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

Re: K152872
Trade/Device Name: K2M Fenestrated Tap System
Regulation Number: 21 CFR 876.1075
Regulation Name: Gastroenterology-urology biopsy instrument
Regulatory Class: Class II
Product Code: KNW, OAR
Dated: November 24, 2015
Received: November 25, 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,

Lori A. Wiggins -S

for
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)*
K152872

Device Name
K2M Fenestrated Tap System

Indications for Use *(Describe)*
The K2M Fenestrated Tap System is intended for use as a standalone biopsy tool to remove a sample of bone tissue from a vertebral body for diagnostic purposes using an aspiration technique, as well as to provide and maintain access to the same surgical site.

When used as a cement dispenser, the K2M Fenestrated Tap System is intended to dispense cement cleared for use in the spine into a vertebral body for vertebral body augmentation using a vertebroplasty procedure.

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
K2M Fenestrated Tap System

Submitter

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

Contact Person: Nancy Giezen
Telephone: 703-777-3155
Date Prepared: 12/02/2015

Classification

Trade Name: K2M Fenestrated Tap System
Common Name: Spinal Fixation System
Regulatory Class: Class II

Classification Name(s):
Gastroenterology-Urology Biopsy Instrument (21 CFR 876.1075, Product Code KNW)
Cement Dispenser (21 CFR 888.4200, Product Code OAR)

Predicate Device(s)

Primary Predicate:
Abbott Spinnaker (K052638)

Device Description

The K2M Fenestrated Tap System consists of surgical instruments designed to access vertebral bodies via a posterior surgical approach.

Function: The K2M Fenestrated Tap System can be used to access the vertebral body for obtaining bone biopsies. This system can also be used for the injection of bone cement into the vertebral body using vertebroplasty or kyphoplasty procedures.

Intended Use

The K2M Fenestrated Tap System is intended for use as a standalone biopsy tool to remove a sample of bone tissue from a vertebral body for diagnostic purposes using an aspiration technique, as well as to provide and maintain access to the same surgical site.

When used as a cement dispenser, the K2M Fenestrated Tap System is intended to dispense cement cleared for use in the spine into a vertebral body for vertebral body augmentation using a vertebroplasty procedure.

Technological Comparison to Predicate(s)
The K2M Fenestrated Tap System was compared to predicate systems and design features such as the materials, number of fenestrations, diameters and thread lengths were found to be substantially the same as these systems.

Non-clinical Performance Evaluation
The functional characteristics were evaluated in cadaver testing and the K2M Fenestrated Tap System was determined achieve its intended use.

Conclusion
There are no significant differences between the K2M Fenestrated Tap System and other systems currently being marketed which would adversely affect the use of the product. It is substantially equivalent to these other devices when comparing materials, number of fenestrations, diameters and thread lengths. In addition the K2M Fenestrated Tap System is being offered for the same intended use as the predicates and was validated via cadaver testing.