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

August 30, 2017

K2M
Nancy Giezen
Manager Regulatory Affairs
600 Hope Parkway SE
Leesburg, Virginia 20175

Re: K171321
Trade/Device Name: K2M Navigation Instruments
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: OLO
Dated: July 31, 2017
Received: August 1, 2017

Dear Nancy 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 (DICE) 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 (DICE) 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,

Katherine D. Kavlock -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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K171321

Device Name
K2M Navigation Instruments

Indications for Use *(Describe)*
K2M Navigation Instruments are intended to be used in the preparation and placement of K2M screws (DENALI, MESA, EVEREST) during spinal surgery to assist the surgeon in precisely locating anatomical structures in either open or minimally invasive procedures. MESA screw navigation is intended for open procedures only. The K2M Navigation Instruments are designed for use with the Medtronic StealthStation® System, which is indicated for any medical condition in which the use of stereotactic surgery may be appropriate, and where reference to a rigid anatomical structure, such as a skull, a long bone, or vertebra, can be identified relative to a CT or MR based model, fluoroscopy images, or digitized landmarks of the anatomy

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 Navigation Instruments

Submitter

K2M
600 Hope Pkwy SE
Leesburg, VA 20175

Contact Person: Nancy Giezen
Telephone: (571) 919-2000
Date Prepared: 7/26/2017

Classification

Trade Name: K2M Navigation Instruments
Common Name: Navigation Instrument
Regulatory Class: Class II

Classification Name(s):
Stereotaxic instrument (21 CFR 882.4560, Product Code OLO)

Predicate Device(s)

Primary Predicate: Medtronic Navigated Instruments (K143375)
Additional Predicates:
Medtronic Medtronic Navigated Instruments (K143628, K143375)
K2M Range/Mesa/Denali Spinal System (K070229, K153031)
K2M Everest Spinal System (K103440, K161369)

Device Description

K2M Navigation Instruments are manual surgical instruments intended be used when implanting previously cleared components of MESA, DENALI and EVEREST Spinal Systems.

Function: These instruments are designed to interface with the Medtronic StealthStation® System when used for navigation during spinal surgery.

Intended Use

K2M Navigation Instruments are intended to be used in the preparation and placement of K2M screws (DENALI, MESA, EVEREST) during spinal surgery to assist the surgeon in precisely locating anatomical structures in either open or minimally invasive procedures. MESA screw navigation is intended for open procedures only. The K2M Navigation Instruments are designed for use with the Medtronic StealthStation® System, which is indicated for any medical condition in which the use of stereotactic surgery may be appropriate, and where reference to a rigid anatomical structure, such as a skull, a long bone, or vertebra, can be identified relative to a CT or MR based model, fluoroscopy images, or digitized landmarks of the anatomy.

Technological Comparison to Predicate(s)

K2M Navigation Instruments were compared to predicate devices and the design features, materials and indications were the same or similar to the previously cleared devices.

Non-clinical Performance Evaluation
Rigidity, registration, and accuracy testing was performed to ensure functionality and compatibility with the Medtronic StealthStation. The results of testing determined that the K2M Navigation Instruments are equivalent to predicate devices.

Conclusion
There are no significant differences between the K2M Navigation Instruments 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.