K2M, Inc.
% Megan Callanan
Regulatory Affairs Associate
Stryker
2 Pearl Court
Allendale, New Jersey 07401

November 14, 2019

Re: K192911
Trade/Device Name: Brainlab Compatible K2M Navigation Instruments
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: OLO
Dated: October 11, 2019
Received: October 15, 2019

Dear Megan Callanan:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

For: Shumaya Ali, MPH
Assistant Director
DHT6C: Division of Restorative, Repair and Trauma Devices
OHT6: Office of Orthopedic Devices
Office of Product Evaluation and Quality
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)*
K192911

Device Name
Brainlab Compatible K2M Navigation Instruments

Indications for Use *(Describe)*

Brainlab Compatible K2M Navigation Instruments are intended to be used in the preparation and placement of K2M pedicle screws (DENALI, MESA, EVEREST, YUKON) during spinal surgery to assist the surgeon in precisely locating anatomical structures in either open or minimally invasive procedures. These instruments are designed for use with the Brainlab Navigation 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. The Brainlab Compatible K2M Navigation Instruments are not intended for navigation of occipital screws.

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.

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510(k) Summary: Brainlab Compatible K2M Navigation Instruments

Submitter:	K2M, Inc. 600 Hope Pkwy SE Leesburg, VA 20175
Contact Person :	Name: Megan Callanan Phone: (551)262-2429 Email: megan.callanan1@stryker.com
Date Prepared:	11/14/2019
Trade Name:	Brainlab Compatible K2M Navigation Instruments
Common Name:	Navigation Instruments
Proposed Class:	Class II
Classification Name:	Orthopedic / Orthopedic Stereotaxic Instruments
Regulation Number:	21 CFR 882.4560
Product Code:	OLO
Predicate Device:	Primary Predicate: Brainlab Compatible K2M Navigation Instruments (K181890)
Device Description:	Brainlab Compatible K2M Navigation Instruments are manual surgical instruments intended be used when implanting previously cleared components of MESA, DENALI, EVEREST and YUKON Spinal Systems. These instruments are designed to interface with the Brainlab Navigation system when used for navigation during spinal surgery. The subject instruments feature a modification of the connection mechanism geometry and material to enhance user experience.
Indications for use:	Brainlab Compatible K2M Navigation Instruments are intended to be used in the preparation and placement of K2M pedicle screws (DENALI, MESA, EVEREST, YUKON) during spinal surgery to assist the surgeon in precisely locating anatomical structures in either open or minimally invasive procedures. These instruments are designed for use with the Brainlab Navigation 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. The Brainlab Compatible K2M Navigation Instruments are not intended for navigation of occipital screws.
Summary of the Technological Characteristics	Brainlab Compatible 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. The subject instruments feature a modification of the connection mechanism geometry and material to enhance user experience.
Non-clinical Performance Evaluation	A risk assessment including sterilization, biocompatibility, and additional rotational testing was conducted to confirm that the subject Brainlab Compatible K2M Navigation Instruments do not introduce new issues of safety or effectiveness.
Conclusion	There are no significant differences between the Brainlab Compatible K2M Navigation Instruments and other legally marketed systems. It is substantially equivalent to these other devices in design, function, material and intended use.