February 6, 2026

K2M, Inc.
Renee Maciag
Staff Regulatory Affairs Specialist
600 Hope Pkwy SE
Leesburg, Virginia 20175

Re: K252873
Trade/Device Name: Q Interbody Instruments
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: OLO
Dated: January 7, 2026
Received: January 7, 2026

Dear Renee Maciag:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13484 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Management System Regulation (QMSR) (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Shumaya Ali -S

Shumaya Ali, M.P.H.
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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K252873

Please provide the device trade name(s).

Q Interbody Instruments

Please provide your Indications for Use below.

VB Spine Q Interbody Instruments are intended to be used as accessories to Stryker's Spine Guidance System to facilitate placement of VB Spine implants. They can be navigated instruments or non-navigated manual instruments. When navigated, VB Spine Q Interbody Instruments are specifically designed for use with Stryker's Spine Guidance Software. They are intended to be used with associated trackers and adaptors to facilitate preparation and placement of VB Spine interbody implants in accordance with the indications and contraindications of the associated VB Spine Implant System and/or Stryker's Spine Guidance System.

Please select the types of uses (select one or both, as applicable).

- ☒ Prescription Use (Part 21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

VB SPINE

510(k) Summary

1 Sponsor Information

Sponsor: K2M, Inc.
600 Hope Parkway SE
Leesburg, VA 20175 USA

Contact Person: Renee Maciag (née Norby)
Staff Regulatory Affairs Specialist
VB Spine
2 Pearl Ct.
Allendale, NJ 07401 USA
Phone: (201) 725-4954
Email: renee.norby@stryker.com

Alternate Contact: Kirsten Reinhold Senior Manager, Regulatory Affairs
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Phone: (201) 831-5903
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Date Prepared: September 8th, 2025

2 Device Name

Subject Device Information	
Trade/Proprietary Name	Q Interbody Instruments
Common Name	Stereotaxic Instruments
Classification	Class II
Classification Product Code	OLO
Classification Name	Orthopedic Stereotaxic Instrument
Classification Regulation	21 CFR 882.4560
Review Panel	Orthopedic

VB SPINE

3 Predicate Device

The following is the legally marketed predicate device for the subject device included in this Traditional 510(k):
Q Pedicle Instruments – K240662

4 Device Description

The Q Interbody Instruments include Q Inserters and Q Interbody Trials, as well as new system components including Q Calibration Devices. The Q Interbody Instruments are intended to be used to facilitate preparation and placement of VB Spine interbody implants.

These instruments are designed to be compatible with Stryker's Spine Guidance 5.3 Software.

5 Indications for Use

VB Spine Q Interbody Instruments are intended to be used as accessories to Stryker's Spine Guidance System to facilitate placement of VB Spine implants. They can be navigated instruments or non-navigated manual instruments. When navigated, VB Spine Q Interbody Instruments are specifically designed for use with Stryker's Spine Guidance Software. They are intended to be used with associated trackers and adaptors to facilitate preparation and placement of VB Spine interbody implants in accordance with the indications and contraindications of the associated VB Spine Implant System and/or Stryker's Spine Guidance System.

6 Comparison of Technological Characteristics

The Q Interbody Instruments are substantially equivalent to the Q Pedicle Instruments in regard to intended use, indications for use, basic design, materials, fundamental scientific technology, and compatibility with navigation software. Verification and validation testing has been completed, and the results confirm no new or different issues of safety and effectiveness have been raised. This information demonstrates that the subject devices are at least as safe and effective as their predicates and, therefore, supports a determination of substantial equivalence.

7 Summary of Non-Clinical Testing

The function and performance of the subject device have been evaluated through non-clinical design verification and validation testing. The results of the evaluation tests demonstrate that the subject device successfully meets the requirements of its intended use, and the subject device demonstrates substantial equivalence to the cited predicate device.

Additional testing was performed on the subject device to ensure it meets its design requirements. A summary of the testing and the results are included below.

- System accuracy verification per ASTM F2554.
- The subject devices were validated with intended users in cadaver labs or simulated use tests to ensure the user needs and intended use requirements were met. All requirements were met and no new issues of safety or effectiveness were raised.
- The subject devices were validated with intended users in cadaver labs to quantify the clinical accuracy and clinically expected error of final implant placement. All requirements were met.

- Biocompatibility verification according to ISO 10993-1:2018 and the FDA Guidance Use of International Standard ISO 10993-1, “Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process, September 2023.
- Sterilization validation of the reusable devices per ISO 17665-1 and the FDA Guidance Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling (March 2015).

8 Summary of Clinical Testing

No clinical testing was required to support this submission.

9 Conclusion

The subject Q Interbody Instruments perform as intended and are substantially equivalent to their respective predicate device with regard to intended use, indications for use, design, principles of operation, technology, materials, performance, and compatibility with navigation software. No new issues of safety or effectiveness have been raised. The performance testing supports a determination of substantial equivalence.