



March 17, 2026

K2m, Inc.
Katie Walko
Staff Regulatory Affairs Specialist
600 Hope Pkwy. SE
Leesburg, Virginia 20175

Re: K260546
Trade/Device Name: Q Pedicle Instruments
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: OLO
Dated: February 18, 2026
Received: February 18, 2026

Dear Katie Walko:

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 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (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 ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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.

K260546

?

Please provide the device trade name(s).

?

Q Pedicle Instruments

Please provide your Indications for Use below.

?

VB Spine Q Pedicle 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 Pedicle Instruments are specifically designed for use with the Spine Guidance Software. They are intended to be used with a Q Navigation Adaptor and associated trackers manually or under power with a Stryker Rotary Handpiece to facilitate pedicle preparation and placement of VB Spine implants in the non-cervical spine in adult and pediatric (adolescent) patients 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 ([21 CFR 801 Subpart D](#))

☐ Over-The-Counter Use ([21 CFR 801 Subpart C](#))

?

Please select the age group(s) for which the device(s) is to be used.

☐ Neonates/Newborns (Birth to < 29 days old)

☐ Infants (29 days old to < 2 years old)

☐ Children (2 years old to < 12 years old)

☒ Adolescents (12 years old to < 22 years old)

☒ Adults (22 years old and greater)

?



510(k) Summary

1 Sponsor Information

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

Contact Person: Katie Walko
Staff Regulatory Affairs Specialist
VB Spine
600 Hope Parkway SE
Leesburg, VA 20175 USA
Phone: (412) 576-3633
Email: katie.walko@vbspineco.com

Alternate Contact: Rachel Rehl
Manager, Regulatory Affairs
VB Spine
600 Hope Parkway SE
Leesburg, VA 20175 USA
Email: rachel.rehl@vbspineco.com

Date Prepared: March 17, 2026

2 Device Name

Subject Device Information	
Trade/Proprietary Name	Q Pedicle 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



3 Predicate Device

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

Reference device for previously cleared compatibility with Mako Spine:
Q Pedicle Instruments – K241517

4 Device Description

The Q Pedicle Instruments include Q Taps and Q Screwdrivers. The Q Pedicle Instruments are intended to be used to facilitate pedicle preparation and screw placement of VB Spine implants.

These instruments are designed to be compatible with Stryker's Spine Guidance 5 Software and Mako Spine System.

5 Indications for Use

VB Spine Q Pedicle 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 Pedicle Instruments are specifically designed for use with the Spine Guidance Software. They are intended to be used with a Q Navigation Adaptor and associated trackers manually or under power with a Stryker Rotary Handpiece to facilitate pedicle preparation and placement of VB Spine implants in the non-cervical spine in adult and pediatric (adolescent) patients 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 purpose of this 510(k) submission is for updates to company branding in the product labeling. The Q Pedicle Instruments are substantially equivalent to the predicate in regard to intended use, indications for use, basic design, materials, fundamental scientific technology, and compatibility with navigation software. Verification and validation testing is not required for the changes summarized in this Special 510(k), and therefore there are no new questions of safety and effectiveness that 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 subject devices in scope of this Special 510(k) were verified and validated and cleared via K240662 and K241517. Since there is no change in indications for use, design, device or navigation software compatibility, technological characteristics, principles of operation, manufacturing process, materials, sterilization, disinfection, or cleaning, additional non-clinical testing is not required. A risk assessment was conducted for the labeling changes to confirm the subject devices do not introduce new issues of safety or effectiveness.

Therefore, no new or different questions of safety and effectiveness have been raised that pose a significant risk to the safety or effectiveness of the subject device.



The Q Pedicle Instruments do not include software. When navigated, they are used with Stryker's Spine Guidance 5 Software.

8 Summary of Clinical Testing

No clinical testing was required to support this submission.

9 Conclusion

The subject Q Pedicle Instruments 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 technological comparison and non-clinical testing rationale support a determination of substantial equivalence.