March 27, 2026

Vy Spine, LLC
Bret Berry
President of Product Development
545 W 500 S., Suite 100
Bountiful, Utah 84010

Re: K260697
Trade/Device Name: VyPlate™ Anterior Cervical Plate System
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal Intervertebral Body Fixation Orthosis
Regulatory Class: Class II
Product Code: KWQ
Dated: March 3, 2026
Received: March 4, 2026

Dear Bret Berry:

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,

STEPHANIE SMITH -S

For Colin O'Neill, M.B.E.
Assistant Director
DHT6B: Division of Spinal 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.	K260697

Please provide the device trade name(s).

VyPlate™ Anterior Cervical Plate System

Please provide your Indications for Use below.

The VyPlate™ Anterior Cervical Plate System is indicated for stabilization of the anterior cervical spine from C2 to C7 employing unicortical screw fixation at the anterior face of the vertebral bodies. Specific clinical indications for anterior plating include:

- instability caused by trauma or fracture;
- instability associated with correction of cervical lordosis and kyphosis deformity;
- instability associated with pseudoarthosis as a result of previously failed cervical spine surgery;
- instability associated with major reconstructive surgery for primary tumors or metastatic malignant tumors of the cervical spine;
- instability associated with single or multiple level corpectomy in advanced degenerative disk disease (defined as discogenic pain with degeneration of the disc confirmed by history and radiographic studies), spinal canal stenosis and cervical myelopathy.

This device is not approved for screw attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic, or lumbar spine.

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

Vy Spine, LLC
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Bountiful, UT 84010
Telephone: 866-489-7746
Fax: 801-294-0079

Contact: Jordan Hendrickson
Operations Manager

17 March 2026

510(k) Number:	K260697
Common or Usual Name:	Anterior Cervical Plate
Proposed Proprietary or Trade Name:	VyPlate™ Anterior Cervical Plate System
Classification Name:	Spinal Intervertebral Body Fixation Orthosis
Regulation Number:	21 CFR 888.3060
Product Code:	KWQ
Primary Predicate:	K221572 VyPlate™ Anterior Cervical Plate System

Substantial Equivalence

The VyPlate™ Anterior Cervical Plate System is substantially equivalent to the VyPlate™ Anterior Cervical Plate System (K221572), in terms of material, intended use, levels of attachment, size range, and strength.

Device Description

The VyPlate™ Anterior Cervical Plate System is comprised of implant, instrument, and tray components. The implant components, the VyPlate™ device, consists of anterior cervical plates with integrated cover plates and bone screws. The implant components of the VyPlate™ Anterior Cervical Plate System are composed of Titanium alloy 6Al-4V as described in ASTM F-136.

Intended Use/Indications for Use

The VyPlate™ Anterior Cervical Plate System is indicated for stabilization of the anterior cervical spine from C2 to C7 employing unicortical screw fixation at the anterior face of the vertebral bodies. Specific clinical indications for anterior plating include:

- instability caused by trauma or fracture;
- instability associated with correction of cervical lordosis and kyphosis deformity;
- instability associated with pseudoarthosis as a result of previously failed cervical spine surgery;
- instability associated with major reconstructive surgery for primary tumors or metastatic malignant tumors of the cervical spine;
- instability associated with single or multiple level corpectomy in advanced degenerative disk disease (defined as discogenic pain with degeneration of the disc confirmed by history and radiographic studies), spinal canal stenosis and cervical myelopathy.

This device is not approved for screw attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic, or lumbar spine.

Performance Data and Substantial Equivalence
The VyPlate™ Anterior Cervical Plate System (K221572) has undergone Non-Clinical Testing using ASTM F1717 Standards at a third party facility. The subject VyPlate™ Anterior Cervical Plate System has the same design, material, and sizes as the predicate devices.

Technological Modifications
The subject VyPlate™ Anterior Cervical Plate System has the same material, design, sizes, indication of use & biocompatibility as the predicate devices, but will be sold as a gamma irradiated sterile packaged product.

Technological Characteristics
The subject VyPlate™ Anterior Cervical Plate System is substantially equivalent to other predicate devices cleared by the FDA for commercial distribution in the United States. The subject device was shown to have equivalent technological characteristics to its predicate devices through comparison in areas including design, intended use, material composition, and function. This device does not contain software or electrical equipment.