July 26, 2022

Vy Spine, LLC
Jordan Hendrickson
Operations Manager
2236 Capital Circle NE, Suite 103-1
Tallahassee, Florida 32308

Re: K221572
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: May 31, 2022
Received: June 1, 2022

Dear Jordan Hendrickson:

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

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K221572

Device Name

VyPlate™ Anterior Cervical Plate System

Indications for Use *(Describe)*

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.

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

Vy Spine, LLC
2236 Capital Circle NE,
Suite 103-1
Tallahassee, FL 32308
Telephone: 866-489-7746
Fax: 850-597-8571

Contact: Jordan Hendrickson
Operations Manager

1 June 2022

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

Substantial Equivalence

The VyPlate™ Anterior Cervical Plate System is substantially equivalent to the primary predicate Reliance Anterior Cervical Plate System (K122216, K140742), 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, 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

Design information and finite element analysis were utilized to establish that the subject VyPlate™ Anterior Cervical Plates have substantially equivalent mechanical strength to the predicate Reliance Anterior Cervical Plate System (K122216, K140742).

Conclusions

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.