



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

December 10, 2021

Re: K213394  
Trade/Device Name: Vy Spine™ VySpan™ PCT System  
Regulation Number: 21 CFR 888.3075  
Regulation Name: Posterior Cervical Screw System  
Regulatory Class: Class II  
Product Code: NKG, KWP  
Dated: October 13, 2021  
Received: October 15, 2021

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](mailto: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

## Indications for Use

510(k) Number (if known)

K213394

Device Name

Vy Spine™ VySpan™ PCT System

Indications for Use (Describe)

Vy Spine™ VySpan™ PCT System, which is used to promote fusion of the cervical spine and the cervicothoracic (C1-T3), is indicated for the following:

- ddd (neck pain of discogenic origin with degeneration of the disc as confirmed by patient history and radiographic studies)
- Spondylolisthesis
- Spinal stenosis
- Fracture/dislocation
- Revision of previous cervical spine surgery
- Tumors

The use of the mini polyaxial screws is limited to placement in the upper thoracic spine (T1-T3) in treating thoracic conditions only. They are not intended to be placed in the cervical spine.

Hooks and Rods

The rod and hook components are also intended to provide stabilization to promote fusion following reduction of fracture/dislocation or trauma in the cervical/upper thoracic (C1-T3) 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.**

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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December 9, 2021

Vy Spine, LLC  
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Telephone: 866-489-7746  
Fax: 850-597-8571

**Contact:** Jordan Hendrickson  
Operations Manager

Common or Usual Name: Spinal Fixation Device  
Proposed Proprietary or Trade Name: Vy Spine™ VySpan™ PCT System  
Classification Name: Posterior cervical screw system (per 21 CFR 888.3075), Spinal interlaminar fixation orthosis (per 21 CFR 888.3050)  
Product Code: NKG, KWP

### **Substantial Equivalence**

The Vy Spine™ VySpan™ PCT System is substantially equivalent to the primary predicate Reliance Posterior Cervical-Thoracic System (K142867), and the additional predicate Reliance Posterior Cervical-Thoracic System (K122292), in terms of material, intended use, levels of attachment, size range, and strength.

### **Device Description**

The Vy Spine™ VySpan™ PCT System is comprised of implant and instrument components. The implant component, the VySpan™ device, consists of posterior attachment elements with a set screw and rod. The VySpan™ pedicle screw component is offered in both poly-axial and mono-axial configuration. In addition to these components, there are also ancillary components such as hooks, connectors, cross-links, and lateral offset connectors. All of the components discussed above are fabricated from Titanium alloy and should not be used with implants of different materials.

### **Intended Use/Indications for Use**

Vy Spine™ VySpan™ PCT System, which is used to promote fusion of the cervical spine and the cervicothoracic (C1-T3), is indicated for the following:

- ddd (neck pain of discogenic origin with degeneration of the disc as confirmed by patient history and radiographic studies)
- Spondylolisthesis
- Spinal stenosis
- Fracture/dislocation
- Revision of previous cervical spine surgery
- Tumors

The use of the mini polyaxial screws is limited to placement in the upper thoracic spine (T1-T3) in treating thoracic conditions only. They are not intended to be placed in the cervical spine.

Hooks and Rods

The rod and hook components are also intended to provide stabilization to promote fusion following reduction of fracture/dislocation or trauma in the cervical/upper thoracic (C1-T3) spine.

#### **Performance Data and Substantial Equivalence**

The Reliance Posterior Cervical-Thoracic System (K122292, K142867) has undergone Non-Clinical Testing using various ASTM Standard tests at a third party facility. The subject Vy Spine™ VySpan™ PCT System has similar design, sizes, indication of use & biocompatibility as the predicate devices.

#### **Technological Modifications**

The subject Vy Spine™ VySpan™ PCT System has similar material, design, sizes, indication of use & biocompatibility as the predicate devices.

#### **Technological Characteristics**

The subject Vy Spine™ VySpan™ PCT 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.