September 27, 2023

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

Re: K232167
Trade/Device Name: VySpan™ PCT System
Regulation Number: 21 CFR 888.3075
Regulation Name: Posterior Cervical Screw System
Regulatory Class: Class II
Product Code: NKG, KWP
Dated: August 29, 2023
Received: August 29, 2023

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 (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 System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 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 systems (QS) regulation (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.

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,

Colin O'neill -S

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K232167

Device Name
VySpan™ PCT System

Indications for Use *(Describe)*
The VySpan™ PCT System, which is used to promote fusion of the cervical spine and the cervicothoracic (C1-T3), and 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.
The VySpan™ PCT System can also be linked to the VyLink™ Screw System using the dual diameter rods and rod-to-rod connectors.

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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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

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

22 July 2023

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

Substantial Equivalence
The VySpan™ PCT System is substantially equivalent to the primary predicate VySpan™ PCT System (K223852) in terms of material, intended use, levels of attachment, size range, and strength.

Device Description
The 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, or Cobalt Chrome, and should not be used with implants of different materials. The purpose of this submission is to add additional connectors and rods to the VySpan™ PCT System.

Intended Use/Indications for Use
The VySpan™ PCT System, which is used to promote fusion of the cervical spine and the cervicothoracic (C1-T3), and 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. The VySpan™ PCT System can also be linked to the VyLink™ Screw System using the dual diameter rods and rod-to-rod connectors.

Performance Data and Substantial Equivalence
Engineering rationale was used to determine no new worse-case was introduced; therefore, no new performance testing has been performed on the subject VySpan™ PCT System. The subject VySpan™ PCT System has the same design, sizes, indication of use & biocompatibility as the predicate devices.

Technological Modifications
The subject VySpan™ PCT System has the same material, design, sizes, indication of use & biocompatibility as the predicate devices. Additional connector and rod components are being added to the VySpan™ PCT System.

Technological Characteristics
The subject 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.