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

February 28, 2022

Re: K213750
Trade/Device Name: VyLink™ Spinal Screw System
Regulation Number: 21 CFR 888.3070
Regulation Name: Thoracolumbosacral Pedicle Screw System
Regulatory Class: Class II
Product Code: NKB, KWP, KWQ
Dated: November 29, 2021
Received: November 30, 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) 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K213750

Device Name
VyLink™ Spinal Screw System

Indications for Use *(Describe)*

The VyLink™ Spinal Screw System is a pedicle screw system intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar, and sacral spine: degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies), degenerative spondylolisthesis with objective evidence of neurological impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (pseudarthrosis).

The VyLink™ Spinal Screw System is also indicated for pedicle screw fixation for the treatment of severe spondylolisthesis (Grades 3 and 4) of the L5–S1 vertebra in skeletally-mature patients receiving fusion by autogenous bone graft and having implants attached to the lumbar and sacral spine (L3 to sacrum) with removal of the implants after the attainment of a solid fusion.

When used posteriorly, the VyLink™ Spinal Screw System is also a hook and sacral/iliac screw fixation system of the noncervical spine indicated for: spondylolisthesis, trauma (fracture and/or dislocation), spinal stenosis, deformities (scoliosis, lordosis and/or kyphosis), tumor, and previous failed fusion (pseudarthrosis). Levels of fixation are for the thoracic, lumbar and sacral spine.

When used in a percutaneous, posterior approach with MIS instrumentation, the VyLink™ Spinal Screw System components are intended for noncervical pedicle fixation and nonpedicle fixation for the following indications: spondylolisthesis, trauma (i.e., fracture or dislocation), spinal stenosis, curvatures (i.e., scoliosis, kyphosis, and/or lordosis), tumor, pseudarthrosis, and failed previous fusion in skeletally-mature patients.

The VyLink™ Spinal Screw System, when used with staples and two rods as an anterior thoracic/lumbar screw fixation system, is indicated for spondylolisthesis, trauma (fracture and/or dislocation), spinal stenosis, deformities (scoliosis, lordosis and/or kyphosis), tumor, and previous-failed fusion (pseudarthrosis).

The Vy Spine™ VySpan™ PCT System can also be linked to the Vy Spine™ VyLink™ Screw System using the dual diameter rods.

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,
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Tallahassee, FL 32308
Telephone: 866-489-7746
Fax: 850-597-8571

Contact: Jordan Hendrickson
Operations Manager

8 February 2022

510k Number:	K23750
Common or Usual Name:	Spinal Fixation Device
Proposed Proprietary or Trade Name:	VyLink™ Spinal Screw System
Classification Name:	Spinal Intervertebral Body Fixation Orthosis (per 21 CFR 888.3060) Spinal Interlaminal Fixation Orthosis (per 21 CFR 888.3050) Thoracolumbosacral Pedicle Screw System (per CFR 888.3070)
Product Code:	NKB, KWP, KWQ

Substantial Equivalence
The VyLink™ Spinal Screw is substantially equivalent to the legally marketed primary predicate Reliance Spinal Screw (K081978, K101112, K110896, K123521, K152131, K162066, and K210874). The VyLink™ Spinal Screw is equivalent to these commercially available devices in terms of material, intended use, levels of attachment, size range, and strength.

Device Description
The VyLink™ Spinal Screw System consists of longitudinal rods, monoaxial screws, polyaxial screws, reduction screws, MIS screws, cannulated screws, fenestrated screws, hooks, reduction hooks, set screws, and transverse connectors.

The VyLink™ Spinal Screw System components are available in titanium alloy conforming to ASTM F-136 specifications. Furthermore, various rods of the Reliance Spinal Screw System are available in Cobalt-Chrome conforming to ASTM F-75 and ASTM F-1537 specifications. The components of one material should not be used with components of another material, with the exception that the Cobalt-Chrome rods may be used with titanium alloy implants. The extension tabs on the reduction and MIS screw and hook components are intended to be removed intraoperatively. The safety and effectiveness of this device has not been established when used in conjunction with bone cement or for use in patients with poor bone quality (e.g., osteoporosis, osteopenia). This device is intended only to be used with saline or radiopaque dye.

Intended Use/Indications for Use
The VyLink™ Spinal Screw System is a pedicle screw system intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar, and

sacral spine: degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies), degenerative spondylolisthesis with objective evidence of neurological impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (pseudarthrosis).
The VyLink™ Spinal Screw System is also indicated for pedicle screw fixation for the treatment of severe
spondylolisthesis (Grades 3 and 4) of the L5–S1 vertebra in skeletally-mature patients receiving fusion by autogenous bone graft and having implants attached to the lumbar and sacral spine (L3 to sacrum) with removal of the implants after the attainment of a solid fusion.
When used posteriorly, the VyLink™ Spinal Screw System is also a hook and sacral/iliac screw fixation system of the noncervical spine indicated for: spondylolisthesis, trauma (fracture and/or dislocation), spinal stenosis, deformities (scoliosis, lordosis and/or kyphosis), tumor, and previous failed fusion (pseudarthrosis). Levels of fixation are for the thoracic, lumbar and sacral spine.
When used in a percutaneous, posterior approach with MIS instrumentation, the VyLink™ Spinal Screw System components are intended for noncervical pedicle fixation and nonpedicle fixation for the following indications: spondylolisthesis, trauma (i.e., fracture or dislocation), spinal stenosis, curvatures (i.e., scoliosis, kyphosis, and/or lordosis), tumor, pseudarthrosis, and failed previous fusion in skeletally-mature patients.
The VyLink™ Spinal Screw System, when used with staples and two rods as an anterior thoracic/lumbar screw fixation system, is indicated for spondylolisthesis, trauma (fracture and/or dislocation), spinal stenosis, deformities (scoliosis, lordosis and/or kyphosis), tumor, and previous-failed fusion (pseudarthrosis).
The Vy Spine™ VySpan™ PCT System can also be linked to the Vy Spine™ VyLink™ Screw System using the dual diameter rods.

Non-Clinical Testing
The predicate Reliance Spinal Screw System has undergone Non-Clinical Testing including Static Compressive, Static Torsion, and Dynamic Compressive in accordance with ASTM F1717. The subject VyLink™ Spinal Screw System has the same design, size range, materials, indications of use, and biocompatibility as the predicate.

Technological Modifications
The subject VyLink™ Spinal Screw 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.