October 13, 2023

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

Re: K231744
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, OUR
Dated: September 15, 2023
Received: September 15, 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)*
K231744

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.

The Ø6.5mm and larger screws may be used for sacroiliac joint fusion. The VyLink™ Spinal Screw System when used in the sacroiliac joint is intended for sacroiliac joint fusion for the following conditions:

• Sacroiliac joint dysfunction that is a direct result of sacroiliac joint disruption and degenerative sacroiliitis. This includes conditions whose symptoms began during pregnancy or in the peripartum period and have persisted postpartum for more than 6 months.

• To augment immobilization and stabilization of the sacroiliac joint in skeletally mature patients undergoing sacropelvic fixation as part of a lumbar or thoracolumbar fusion.

• Acute, non-acute, and non-traumatic fractures involving the sacroiliac joint

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

29 Sep 2023

Contact: Jordan Hendrickson
Operations Manager

510k Number:	
Common or Usual Name:	Spinal Fixation Device
Proposed Proprietary or Trade Name:	VyLink™ Spinal Screw System
Classification Name:	Smooth or threaded metallic bone fixation fastener (per 21 CFR 888.3040) Spinal Interlaminal Fixation Orthosis (per 21 CFR 888.3050) Spinal Intervertebral Body Fixation Orthosis (per 21 CFR 888.3060) Spondylolisthesis Spinal Fixation Device System and Pedicle Screw System (per CFR 888.3070)
Product Code:	NKB, KWP, KWQ, OUR

Substantial Equivalence

The VyLink™ Spinal Screw is substantially equivalent to the legally marketed primary predicate VyLink™ Spinal Screw System (K213750) and the additional predicate device SI-BONE iFuse Bedrock Granite Implant System (K222774). 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.

Indications for Use Statement

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).

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- To augment immobilization and stabilization of the sacroiliac joint in skeletally mature patients undergoing sacropelvic fixation as part of a lumbar or thoracolumbar fusion.
- Acute, non-acute, and non-traumatic fractures involving the sacroiliac joint

Non-Clinical Testing

No new performance testing has been performed on the subject VyLink™ Spinal System. The subject VyLink™ Spinal System has similar design, materials, sizes, indication of use & biocompatibility as the predicate devices.

Technological Modifications
The subject VyLink™ Spinal System has the same or similar material, design, sizes, indication of use & biocompatibility as the predicate devices.
Additional indications are being added to the VyLink™ Spinal System.

Conclusion
The subject VyLink™ Spinal 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.