October 16, 2024

Vy Spine, LLC
Jordan Hendrickson
Quality Operations Manager
545 W 500 South, Suite 100
Bountiful, Utah 84011

Re: K242784
Trade/Device Name: Vy Spine™ VyLam™ Laminoplasty System
Regulation Number: 21 CFR 888.3050
Regulation Name: Spinal interlaminal fixation orthosis
Regulatory Class: Class II
Product Code: NQW
Dated: September 16, 2024
Received: September 16, 2024

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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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,

Brent Showalter -S

Brent Showalter, Ph.D.
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K242784

Device Name
Vy Spine™ VyLam™ Laminoplasty System

Indications for Use *(Describe)*
The Vy Spine™ VyLam™ Laminoplasty System is indicated for use in laminoplasty of the lower cervical and upper thoracic spine (C3 to T3) in skeletally mature patients. The system devices are designed for use with allogenic bone graft in order to prevent the allograft from expulsion or impinging on the spinal cord. One device may be used per vertebra.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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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
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Bountiful, UT 84010
Telephone: (866) 489-7746
Fax: (850) 597-8571

16 October 2024

Contact: Jordan Hendrickson, Operations Manager

Common or Usual Name:	Interlaminal Fixation Appliance
Proposed Proprietary or Trade Name:	Vy Spine™ VyLam™ Laminoplasty System
Classification Name:	Spinal Interlaminal Fixation Orthosis
Regulation Number:	21 CFR 888.3050
Product Code:	NQW
Primary Predicate:	Vy Spine™ VyLam™ Laminoplasty System (K232471)
Additional Predicate:	CENTERPIECE™ Plate Fixation System (K050082)

Substantial Equivalence:
The subject Vy Spine™ VyLam™ Laminoplasty System is substantially equivalent to the primary predicate Vy Spine™ VyLam™ Laminoplasty System (K232471) and the additional predicate CENTERPIECE™ Plate Fixation System (K050082) in terms of intended use, indications for use, function, principle of operation, materials, size range, and strength.

Purpose:
The purpose of this Special 510(k) submission is for the addition of implant plates to the Vy Spine™ VyLam™ Laminoplasty System. These additional plates include: VyLam™ Double Hook Plate, VyLam™ Inline Double Hook Plate, and VyLam™ Support Plate.

Device Description:
The Vy Spine™ VyLam™ Laminoplasty System is comprised of implant and instrument components. The implant components, plates and screws, will hold the decompression after a laminoplasty procedure. The implant components are manufactured from Ti-6Al-4V ELI per ASTM F136 and are available in multiple anatomical sizes to accommodate various vertebral

bodies. The instruments are manufactured from stainless steel per ASTM F899, high grade plastic, and silicone rubber.

Indications for Use:
The Vy Spine™ VyLam™ Laminoplasty System is indicated for use in laminoplasty of the lower cervical and upper thoracic spine (C3 to T3) in skeletally mature patients. The system devices are designed for use with allogenic bone graft in order to prevent the allograft from expulsion or impinging on the spinal cord. One device may be used per vertebra.

Technological Modifications:
The subject Vy Spine™ VyLam™ Laminoplasty System's technological characteristics are the same as or similar to the predicate devices commercially distributed.

Performance Data and Substantial Equivalence:
FEA analyses for the additional plates' four-point bending (based on ASTM F2193) were performed to compare the strength of the additional plates to the standard plate in the predicate Vy Spine™ VyLam™ Laminoplasty System (K232471). The performance data verifies that the subject is substantially equivalent to the predicate Vy Spine™ VyLam™ Laminoplasty System (K232471).