



March 19, 2026

Vy Spine, LLC
Jordan Hendrickson
Director of Quality Assurance
545 W 500 South
Suite 100
Bountiful, Utah 84010

Re: K253432
Trade/Device Name: DiversiVy™ Facet Screw System
Regulatory Class: Unclassified
Product Code: MRW
Dated: October 1, 2025
Received: October 1, 2025

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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,

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

Indications for Use

Submission Number (if known)

K253432

Device Name

DiversiVy™ Facet Screw System

Indications for Use (Describe)

The DiversiVy™ Facet Screw System is intended to stabilize the spine as an aid to fusion by transfacet fixation. The device is indicated for posterior surgical treatment with or without bone graft, at single or multiple levels from L1 to S1 (inclusive), for any or all of the following: Spondylolisthesis, Spondylolysis, Pseudoarthrosis or failed previous fusions which are symptomatic, Degenerative Disc Disease (DDD) as defined by back pain of discogenic origin with degeneration of disc confirmed by history and radiographic studies and/or degenerative disease of the facets with instability.

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

16 March 2026

545 W 500 South

Suite 100

Bountiful, UT 84010

Telephone: 866-489-7746

Fax: 801-294-0079

Contact: Jordan Hendrickson
Operations Manager

510(k) Number: K253432

Common or Usual Name: Facet Screw Spinal Device Proposed

Proprietary or Trade Name: DiversiVy™ Facet Screw System

Classification Name: Unclassified

Regulation Number: NA

Product Code: MRW

Device Description

The DiversiVy™ Facet Screw System is comprised of implants components. The implant component, the DiversiVy™ Facet Screw, is an assortment of screws, which insert through the facets of two adjacent spinal vertebral bodies. The DiversiVy™ Facet Screw is made from Titanium Alloy conforming to ASTM F-136.

Indications for Use

The DiversiVy™ Facet Screw System is intended to stabilize the spine as an aid to fusion by transfacet fixation. The device is indicated for posterior surgical treatment with or without bone graft, at single or multiple levels from L1 to S1 (inclusive), for any or all of the following: Spondylolisthesis, Spondylolysis, Pseudoarthrosis or failed previous fusions which are symptomatic, Degenerative Disc Disease (DDD) as defined by back pain of discogenic origin with degeneration of disc confirmed by history and radiographic studies and/or degenerative disease of the facets with instability.

Performance Testing

Substantially equivalent mechanical performance of the DiversiVy™ Facet Screw System components was demonstrated through engineering analysis of the relative bending

strength and axial pullout strength of the worst case subject screws compared to legally marketed predicates.

Substantial Equivalence

The DiversiVy™ Facet Screw System is substantially equivalent to the primary predicate device Spinal USA Facet Screw System (K130863). The DiversiVy™ Facet Screw System is equivalent to commercially available devices in terms of material, intended use, levels of attachment, and size range.

Summary

The subject DiversiVy™ Facet 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.