



November 4, 2022

Vy Spine, LLC
Mr. Jordon Henderson
Member-Manager
2236 Capital Circle NE, Suite 103-1
Tallahassee, Florida 32308

Re: K221162

Trade/Device Name: UniVy™ OsteoVy™ Cervical IBF System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: ODP
Dated: September 30, 2022
Received: October 5, 2022

Dear Mr. Henderson:

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,

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

Indications for Use

510(k) Number (if known)
K221162

Device Name
Vy Spine™ UniVy™ OsteoVy™ Cervical IBF System

Indications for Use (Describe)

The UniVy™ OsteoVy™ Cervical IBF System is indicated for intervertebral body fusion of the spine in skeletally mature patients. The system devices are designed for use with autogenous bone graft to facilitate fusion. One device may be used per intervertebral space. The implants are intended to be used with legally cleared supplemental spinal fixation cleared for the implanted level.

The UniVy™ OsteoVy™ Cervical IBF System is intended for use at one level in the cervical spine, from C3 to T1, for treatment of cervical degenerative disc disease (DDD is defined as neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies). The UniVy™ OsteoVy™ Cervical IBF System is to be used in patients who have six weeks of non-operative treatment.

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

19 April 2022

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

510(k) Number:

Common or Usual Name:	Intervertebral Body Fusion Device
Proposed Proprietary or Trade Name:	UniVy™ OsteoVy™ Cervical IBF System
Classification Name:	Intervertebral Body Fusion Device
Regulation Number:	21 CFR 888.3080
Product Code:	ODP

Substantial Equivalence:

The subject UniVy™ OsteoVy™ Cervical IBF System is substantially equivalent to the legally marketed primary predicate device, the Reliance Cervical IBF System (K202266) and the secondary predicate devices, Nexxt Spine Matrixx™ System (K171140) and Vy Spine ClariVy™ Cervical IBF System (K212715). The subject UniVy™ OsteoVy™ Cervical IBF System is equivalent to its commercially available predicate in terms of intended use, indications for use, design, function, principle of operation, materials, levels and methods of attachment, size range, strength, methods of manufacturing and sterilization, and use with supplemental fixation.

Device Description:

The UniVy™ OsteoVy™ Cervical IBF System is comprised of implant components. The implant component is a spacer which inserts between vertebral bodies in the anterior column of the cervical spine. The subject UniVy™ OsteoVy™ Cervical IBF spacer is comprised of additively manufactured Titanium 6Al-4V ELI conforming to ASTM F3001-14.

Intended Use / Indications for Use:

The UniVy™ OsteoVy™ Cervical IBF System is indicated for intervertebral body fusion of the spine in skeletally mature patients. The system devices are designed for use with autogenous bone graft to facilitate fusion. One device may be used per intervertebral space. The implants are

intended to be used with legally cleared supplemental spinal fixation cleared for the implanted level.

The UniVy™ OsteoVy™ Cervical IBF System is intended for use at one level in the cervical spine, from C3 to T1, for treatment of cervical degenerative disc disease (DDD is defined as neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies). The UniVy™ OsteoVy™ Cervical IBF System is to be used in patients who have six weeks of non-operative treatment.

Non-Clinical Testing:

The predicate Reliance Cervical IBF System (K202266) has undergone non-clinical testing using various ASTM standards at a third party facility. The subject UniVy™ OsteoVy™ Cervical IBF System has the same material, general design, sizes, indication of use and biocompatibility as the primary predicate device, and the predicate device performance test results will be leveraged in favor of the UniVy™ OsteoVy™ Cervical IBF System.

Technological Modifications:

The UniVy™ OsteoVy™ Cervical IBF System intends to market the primary predicate device design, with the only design change being a reduction to the diameter of the implant inserter holes. The subject UniVy OsteoVy Cervical IBF system is substantially equivalent to the predicate devices in terms of sterilization and biocompatibility.

Technological Characteristics:

The subject UniVy™ OsteoVy™ Cervical IBF System is substantially equivalent to other predicate devices cleared by the FDA for commercial distribution in the United States. The subject device has equivalent technological characteristics to its predicate devices in areas including design, intended use, material composition, and function. This device does not contain software or electrical equipment.