April 18, 2023

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

Re: K223513
Trade/Device Name: UniVy™ OsteoVy™-Ti Cervical IBF System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: ODP
Dated: March 20, 2023
Received: March 21, 2023

Dear Mr. 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,

Katherine D. Kavlock -S

for
Brent L. 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)*
K223513

Device Name
UniVy™ OsteoVy™-Ti Cervical IBF System

Indications for Use *(Describe)*
The UniVy™ OsteoVy™-Ti 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™-Ti 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™-Ti 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

Vy Spine, LLC
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Telephone: (866) 489-7746
Fax: (850) 597-8571

11 April 2023

Contact: Jordan Hendrickson
Operations Manager

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

Substantial Equivalence:
The subject UniVy™ OsteoVy™-Ti NanoVy™-HA Cervical IBF components are substantially equivalent to the legally marketed primary predicate device UniVy™ OsteoVy™-Ti Cervical IBF System (K221162) and the secondary predicate device Alphatec IdentiTi NanoTec (K220782). The subject UniVy™ OsteoVy™-Ti NanoVy™-HA Cervical IBF components are 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™-Ti 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™-Ti Cervical IBF System spacer is comprised of additively manufactured Titanium 6Al-4V ELI conforming to ASTM F3001-14. The UniVy™ OsteoVy™-Ti NanoVy™-HA Cervical IBF components' surfaces have been treated with a 20-40 nanometer thin hydroxyapatite (HA) surface treatment. The surface treatment presents nano-scale topography on the entirety of the implant surface, in addition to macro-/micro-scale topography existing from prior to treatment.

Intended Use / Indications for Use:
The UniVy™ OsteoVy™-Ti 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™-Ti 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™-Ti Cervical IBF System is to be used in patients who have six weeks of non-operative treatment.

Non-Clinical Testing:
Mechanical testing performed on the predicates applies to the modified devices because there is no difference in size, dimension, raw material or manufacturing method or equipment with the exception of a nanometer thin layer of hydroxyapatite applied to the surface.
Nonclinical testing performed on the UniVy™ OsteoVy™-Ti NanoVy™-HA Cervical IBF System supports substantial equivalence to other predicate devices. The following testing was performed:
• Bacterial endotoxin testing (BET) per ANSI/AAMI ST72:2011/(R)2016
• Device-specific adhesion testing of HA nanocoating surface integrity
The results demonstrate that the subject UniVy™ OsteoVy™-Ti NanoVy™-HA Cervical IBF System is substantially equivalent to other predicate devices for nonclinical testing.

Technological Modifications:
The subject UniVy™ OsteoVy™-Ti NanoVy™-HA Cervical IBF components incorporate a nano-scale hydroxyapatite surface treatment, identical to that provided on devices cleared in IdentiTi NanoTec. The UniVy™ OsteoVy™-Ti NanoVy™-HA Cervical IBF System implants contain a itanium alloy structure that is treated with nano-scale hydroxyapatite surface treatment, this material and nano-scale coating is identical to screws cleared in predicate Alphatec IdentiTi NanoTec (K220782). The indications for use are substantially equivalent to predicate devices.
The technological design features of the subject implants were compared to the predicates in intended use, indications for use, design, function and technology and it was demonstrated that they are substantially equivalent.

Conclusion:
The subject UniVy™ OsteoVy™-Ti NanoVy™-HA Cervical IBF components are 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.