January 6, 2023

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

Re: K223412
Trade/Device Name: LumiVy™ Lumbar IBF System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: MAX
Dated: November 9, 2022
Received: November 9, 2022

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 (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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K223412

Device Name
LumiVy™ Lumbar IBF System

Indications for Use *(Describe)*
The LumiVy™ Lumbar IBF System is indicated for intervertebral body fusion of the spine in skeletally mature patients. The device systems are designed for use with autogenous bone graft to facilitate fusion. The implants are intended to be used with legally cleared supplemental spinal fixation cleared for the implanted level.

The LumiVy™ Lumbar IBF System is also intended for use at either one level or two contiguous levels in the lumbar spine, from L2 to S1, for the treatment of degenerative disc disease (DDD) with up to Grade 1 spondylolisthesis. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The lumbar device is to be used in patients who have had six months of non-operative treatment.

Additional supplemental fixation is not necessary for the LumiVy™ -AS implants if the integrated screws are implanted.

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

Contact: Jordan Hendrickson
Operations Manager

23 November 2022

Common or Usual Name:	Intervertebral Body Fusion Device
Proposed Proprietary or Trade Name:	LumiVy™ Lumbar IBF System
Classification Name:	Class II, Intervertebral Body Fusion Device
Regulation Number:	21 CFR 888.3080
Product Code:	MAX

Substantial Equivalence

The LumiVy™ NanoVy™ Ti Lumbar IBF System is substantially equivalent to the primary predicate device LumiVy™ Lumbar IBF System (K212930) and the secondary predicate SeaSpine NanoMetalene Spacer System (K200879, K193636, K192132, K181079, K173606, K173260, K142488). The LumiVy™ NanoVy™ Ti Lumbar IBF System is equivalent to these commercially available devices in terms of material, intended use, levels of attachment, size range, and use with supplemental fixation.

Device Description

The LumiVy™ Lumbar IBF System device is intended to be used as an intervertebral body fusion device. The device is surgically implanted between vertebral bodies from an anterior, lateral, or posterior surgical approach. These devices also contain Tantalum wires to aid in fluoroscopic visualization. The LumiVy™ Lumbar IBF System device is available in multiple anatomical shapes and sizes, to accommodate various vertebral bodies. These include smaller cylindrical and rectangular shapes, elongated elliptical shapes, and larger hemi-cylindrical shapes. The spacer may be made of PEEK Optima LT1 or PEEK Optima LT1-HA with Tantalum markers. The LumiVy™ NanoVy™ Ti Lumbar IBF components are made of PEEK Optima LT1 with CP Titanium coating. The LumiVy™ Lumbar IBF System may also include bone screws manufactured from Titanium alloy to secure the device to the vertebral body.

Intended Use/Indications for Use

The LumiVy™ Lumbar IBF System is indicated for intervertebral body fusion of the spine in skeletally mature patients. The device systems are designed for use with autogenous bone graft to facilitate fusion. The implants are intended to be used with legally cleared supplemental spinal fixation cleared for the implanted level.

The LumiVy™ Lumbar IBF System is also intended for use at either one level or two contiguous levels in the lumbar spine, from L2 to S1, for the treatment of degenerative disc disease (DDD) with up to Grade 1 spondylolisthesis. DDD is defined as back pain of discogenic origin with

degeneration of the disc confirmed by history and radiographic studies. The lumbar device is to be used in patients who have had six months of non-operative treatment.
Additional supplemental fixation is not necessary for the LumiVy™ -AS implants if the integrated screws are implanted.

Non-Clinical Testing
No additional testing was performed on the LumiVy™ NanoVy™ Ti Lumbar IBF components.

Technological Modifications
The subject LumiVy™ NanoVy™ Ti Lumbar IBF System differs from the primary predicate devices in terms of CP titanium coating.

Technological Characteristics
The subject LumiVy™ NanoVy™ Ti Lumbar IBF components are 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.