



September 24, 2024

Vy Spine, LLC
Jordan Hendrickson
Quality Operations Manager
545 W 500 South, Suite 100
Bountiful, Utah 84010

Re: K233807

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, OVD
Dated: August 20, 2024
Received: August 20, 2024

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 (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,

Katherine D. Kavlock -

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for

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)
K233807

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.

Hyperlordotic interbody devices (>20° lordosis) must be used with at least anterior supplemental fixation or anterior buttress plate with posterior supplemental fixation.

Additional supplemental fixation is not necessary for the LumiVy™ -AS implants if the integrated screws are implanted for cages with a lordosis of less than or equal to 20°.

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.

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510(k) Summary

23 Aug 2024

Vy Spine, LLC
545 W 500 South
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Bountiful, UT 84010
Telephone: 866-489-7746
Fax: 850-597-8571

Contact: Jordan Hendrickson
Operations Manager

510(k) Number:	K233807
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, OVD

Substantial Equivalence

The LumiVy™ NanoVy™ Ti Lumbar IBF System is substantially equivalent to the primary predicate device LumiVy™ Lumbar IBF System (K212930, K223412) and the secondary predicate devices ClariVy OsteoVy PEKK (K212715, K230414, K231836), RTI FortiLink (K172343), and SeaSpine Meridian System (K200879). 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 purpose of this 510(k) submission is to introduce the LumiVy™ OsteoVy™ PEKK Lumbar IBF configuration. 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™ OsteoVy™ PEKK Lumbar IBF is made from OXPEKK. The LumiVy™ Lumbar IBF System may also include bone screws manufactured from Titanium alloy to secure the device to the vertebral body. Additionally, this submission adds hyper-lordotic options to the LumiVy™ System.

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.

Hyperlordotic interbody devices ($>20^\circ$ lordosis) must be used with at least anterior supplemental fixation or anterior buttress plate with posterior supplemental fixation

Additional supplemental fixation is not necessary for the LumiVy™ -AS implants if the integrated screws are implanted for cages with a lordosis of less than or equal to 20° .

Non-Clinical Testing

Mechanical testing was performed on the LumiVy™ OsteoVy™ PEKK Lumbar IBF components. Specifically, Static and Dynamic Axial Compression and Compression Shear Testing per ASTM F2077 and Static Subsidence Testing per ASTM F2267.

Technological Modifications

The subject LumiVy™ OsteoVy™ PEKK Lumbar IBF System differs from the primary predicate devices in terms of utilizing OXPEKK material. Additionally, this submission adds hyper-lordotic and smaller ALIF options to the LumiVy™ System.

Technological Characteristics

The subject LumiVy™ OsteoVy™ PEKK 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.

Conclusions

The nonclinical tests demonstrate that the LumiVy™ OsteoVy™ PEKK Lumbar IBF is as safe, as effective, and performs as well or better than a legally marketed predicate device.