October 30, 2023

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

Re: K231836
Trade/Device Name: ClariVy™ Cervical IBF System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: ODP, OVE
Dated: October 12, 2023
Received: October 13, 2023

Dear Mr. 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 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.

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 -S

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

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)*
K231836

Device Name
ClariVy™ Cervical IBF System

Indications for Use *(Describe)*

The ClariVy™ Cervical 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. 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 ClariVy™ Cervical IBF System is intended for use at one level in the cervical spine, from C3 to Tl, for treatment of cervical degenerate disc disease (DDD is defined as neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies). The ClariVy™ 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.

510(k) Summary

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Contact: Jordan Hendrickson
Operations Manager

30 October 2023

510(k) Number:	K231836
Common or Usual Name:	Intervertebral Body Fusion Device
Proposed Proprietary or Trade Name:	ClariVy™ Cervical IBF System
Classification Name:	Intervertebral Body Fusion Device
Regulation Number:	21 CFR 888.3080
Product Code:	ODP, OVE
Regulatory Classification:	Class II

Substantial Equivalence

The ClariVy™ Cervical IBF System is substantially equivalent to the primary predicate device the ClariVy™ Cervical IBF System (K230414, K212715), and the secondary device, RTI Surgical FortiLink-C (K163673). The ClariVy™ Cervical 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 ClariVy™ OsteoVy™ PEKK Cervical IBF configuration. The ClariVy™ Cervical IBF System is comprised of implants components. The implant component, the ClariVy™ Cervical IBF device, is a spacer, which inserts between vertebral bodies in the anterior column of the cervical spine. The spacer may be made of PEEK Optima LT1 or PEEK Optima LT1-HA with Tantalum markers. The ClariVy™ NanoVy™ Ti Cervical IBF components are made of PEEK Optima LT1 with CP Titanium coating. The ClariVy™ Cervical IBF and ClariVy™ NanoVy™ Ti may also include Titanium alloy bone screws to secure the device to the vertebral body. The ClariVy™ OsteoVy™ PEKK Cervical IBF is made from OXPEKK.

Intended Use/Indications for Use

The ClariVy™ Cervical 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. 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 ClariVy™ Cervical IBF System is intended for use at one level in the cervical spine, from C3 to T1, for treatment of cervical degenerate disc disease (DDD is defined as neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies).

The ClariVy™ Cervical IBF System is to be used in patients who have six weeks of non-operative treatment.

Non-Clinical Testing
The ClariVy™ OsteoVy™ PEKK devices has undergone Non-Clinical Testing using various ASTM Standards at a third party facility. Mechanical testing was performed on the ClariVy™ OsteoVy™ PEKK System following ASTM F-2077 standards. These mechanical tests included static and dynamic axial compression, static and dynamic axial torsion, and static dynamic compressive shear, and well as push-out and subsidence testing.

Technological Modifications
The subject ClariVy™ OsteoVy™ PEKK Cervical IBF System differs from the primary predicate devices in terms of utilizing OXPEKK material.

Technological Characteristics
The subject ClariVy™ Cervical IBF 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. This device does not contain software or electrical equipment.

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