May 6, 2024

Vertos Medical Inc
Lisa Maloney
Principal Regulatory Affairs Specialist
95 Enterprise Unit 325
Aliso Viejo, California 92656

Re: K233800
Trade/Device Name: Vertos mild Device Kit (MDK-0002)
Regulation Number: 21 CFR 888.1100
Regulation Name: Arthroscope
Regulatory Class: Class II
Product Code: HRX, HAE
Dated: November 28, 2023
Received: November 29, 2023

Dear Lisa Maloney:

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,

Jesse Muir -S

Digitally signed by Jesse Muir -S
Date: 2024.05.06 13:11:36 -04'00'

Jesse Muir, Ph.D.
Assistant Director
DHT6C: Division of Restorative, Repair and Trauma 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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K233800

Device Name

Vertos mild Device Kit (MDK-0002)

Indications for Use *(Describe)*

The Vertos Medical mild Device Kit is a set of specialized surgical instruments intended to be used to perform lumbar decompressive procedures for the treatment of various spinal conditions.

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 (21 CFR §807.92)
Vertos Medical, Inc. *mild* Device Kit

I. Submitter Information

Company Name:	Vertos Medical, Inc.
Company Address:	95 Enterprise, Ste. 325 Aliso Viejo, CA 92656 Phone: 949-349-0008
Primary Contact:	Lisa Maloney Director of RA/QA Phone: (949) 538-5252 Email: lmaloney@vertosmed.com

Date Prepared: May 2, 2024

II. Device Information

Device Trade Name:	Vertos Medical *mild* Device Kit (MDK-0002)
Device Common Name:	Arthroscopic Accessories
Regulation Number:	21 CFR §888.1100
Regulation Name:	Arthroscope
Regulatory Classification:	Class II
Product Code:	HRX, HAE
Classification Panel:	Orthopedic

III. Predicate Device Information (510(k) K093062)

Device Trade Name:	Vertos Medical *mild* Device Kit (MDK-0001)
Device Common Name:	Arthroscopic Accessories
Regulation Number:	21 CFR §888.1100
Regulation Name:	Arthroscope
Regulatory Classification:	Class II
Product Code:	HRX, HAE
Classification Panel:	Orthopedic

IV. Device Description

The Vertos Medical *mild* Device Kit is a sterile, single-use device. The *mild* Device is composed of surgical tools consisting of one each of the following components: *mild* Initiator, *mild* Access Auger, *mild* Bone Rongeur, and *mild* Tissue Sculpter.

The *mild* Initiator is pre-assembled for convenience and includes: the *mild* Trocar and Handle, *mild* Portal, *mild* Portal Grip, and *mild* Depth Guide.

The *mild* Device Kit is utilized for tissue access, retraction, and resection within the lumbar spine via a minimally invasive posterior approach. The procedure is conducted percutaneously with the *mild* Tissue Sculpter and Bone Rongeur, placed through an introducer cannula, the *mild* Portal. Fluoroscopic imaging in the Anterior-Posterior (AP) caudal-cranial and lateral-oblique planes is utilized to assess anatomical landmarks and guide the instruments to the lamina and into the ligamentum flavum in the posterior spine for tissue and bone removal.

V. Indications for Use

The Vertos Medical *mild* Device Kit is a set of specialized surgical instruments intended to be used to perform lumbar decompressive procedures for the treatment of various spinal conditions.

VI. Comparison of Technological Characteristics with the Predicate Device

The subject device and the predicate share the same intended use and have similar technological characteristics.

Key differences between the subject and predicate devices are reflected in the following table.

	Subject Device **Vertos Medical *mild* Device Kit** **(MDK-0002)**	**Predicate Device** **Vertos Medical *mild* Device Kit** **(MDK-0001)**
Indications for Use	The Vertos Medical *mild* Device Kit is a set of specialized surgical instruments intended to be used to perform lumbar decompressive procedures for the treatment of various spinal conditions.	**Same**

	Subject Device **Vertos Medical *mild* Device Kit** **(MDK-0002)**	**Predicate Device** **Vertos Medical *mild* Device Kit** **(MDK-0001)**
Primary Device Components / Materials	***mild* Access Auger** • Polyphenylene, glass fiber reinforced • Stainless steel	**Not included**
	***mild* Bone Rongeur** • Polyphenylene, glass fiber reinforced • Stainless steel	**Same**
	***mild* Tissue Sculpter** • Acrylonitrile butadiene styrene • Stainless steel • Nylon • Zinc-plated wire	**Same**
	***mild* Initiator (includes Trocar, Handle, Portal, Portal Grip, Depth Guide)** • Acrylonitrile butadiene styrene • Acrylonitrile butadiene styrene+polycarbonate • Polycarbonate • Stainless steel • Thermoplastic elastomer ***combines all 4 predicate device components into one**	***mild* Trocar and Handle** • Acrylonitrile butadiene styrene • Stainless steel • Thermoplastic elastomer
		mild Portal • Acrylonitrile butadiene styrene • Stainless steel • Thermoplastic elastomer
		***mild* Portal Stabilizer** • Acrylonitrile butadiene styrene • Acrylonitrile butadiene styrene+polycarbonate
		***mild* Depth Guide** • Acrylonitrile butadiene styrene • Polycarbonate

VII. Performance Tests

Per the design control requirements specified in 21 CFR §820.30, the subject device met all predetermined acceptance criteria for the following performance tests, demonstrating substantial equivalence to the predicate device.

- **Simulated use cadaveric testing** demonstrated the instruments can be used to safely and effectively perform the *mild* procedure.
- **The bench testing** demonstrated the safety and efficacy of the instruments and their strength and integrity to resist impact, insertion, removal, and rotational loads to perform the stated intend use.
- **Shelf life and packaging** testing demonstrated the safety and reliability of the labeled shelf life of Vertos Medical *mild* Device Kit per ASTM F1886/F1886M, ASTM F2096, ASTM D4169 and ASTM F88/MF88
- **Biocompatibility** testing demonstrated the safety of the Vertos Medical *mild* Device Kit per ISO 10993 -1:2018
- **Sterility Testing** demonstrated the safety and effectiveness of the Vertos Medical *mild* Device Kit sterilization process per ISO 11137-1:2015 + A2:2019.
- **Particulate Testing** demonstrated that the instruments do not produce foreign particulates during device interaction in excess of requirements per AAMI TIR42:2021

VIII. Conclusion

Based on the Indications for Use, design, technological characteristics, and results of safety and performance testing, the subject Vertos Medical *mild* Device Kit meets the requirements for its intended use and is substantially equivalent to the predicate device.