August 10, 2022

VisionCare Devices, LLC.
% Rick Morgan
Owner
VisonCare Devices, LLC
6100 Bellevue Lane
Anderson, California 96007

Re: K212763
Trade/Device Name: UniVit™ HE, UniVit™ UHS
Regulation Number: 21 CFR 886.4150
Regulation Name: Vitreous Aspiration And Cutting Instrument
Regulatory Class: Class II
Product Code: HQE
Dated: July 5, 2022
Received: July 8, 2022

Dear Rick Morgan:

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,

Anjana Jain, PhD
Assistant Director
DHT1A: Division of Ophthalmic Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT and Dental 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)*
K212763

Device Name
UniVit HE™, UniVit™ UHS

Indications for Use *(Describe)*
The UniVit™ HE and UniVit™ UHS are single use (disposable) products intended for use in both anterior and posterior segment (vitrectomy) ophthalmic surgeries when used with a pneumatically-driven vitrectomy system or phacoemulsification system that has a pneumatically-driven vitrectomy module.

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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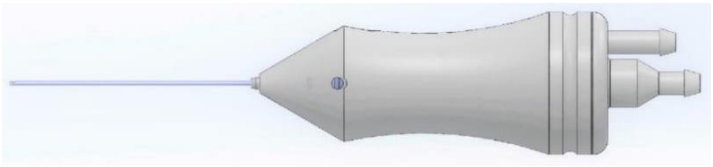
510(k) Summary

SUBMITTER			
Date Prepared	8/10/2022		
Submitter/Owner	**VisionCare Devices, LLC.** 6100 Bellevue Lane Anderson, California 96007 +1-530-364-2271 Phone +1-530-364-2275 Fax		
Key Contact	Rick Morgan Owner Rick@VitCutter.com +1-530-364-2271		
510(k) Submission Type	This is a Traditional 510(k).		
DEVICE			
Trade Name	UniVit™ HE and UniVit™ UHS		
Common Name	Vitreous Cutter		
Classification Name	Class II Panel 86: Ophthalmic Subpart E: Surgical Devices 886.4150 Vitreous Aspiration and cutting instrument Procode: HQE		
PREDICATE DEVICE			
Predicate Device	***510(k) No.***	***Company Name*** ***Device Name***	***Product Code***
	K120170	VisionCare Devices, Inc. ProCare HSP	***HQE***
Reference Device	K190875	DORC EVA	***HQC, HQE***
The UniVit™ is substantially equivalent to the legally marketed predicate VisionCare Devices, Inc. ProCare HSP Vitcutter; K120170.			
DEVICE DESCRIPTION			
UniVit™ HE and UniVit™ UHS – description of the device per 21 CFR 807.92(a) (4)			
The operation of a vitreous cutter is simple. An air pulse pushes down the diaphragm located inside the vitrectomy probe, leading the port to a closed position (the guillotine movement); at the same time, a spring is compressed and forces the diaphragm back to the open port position. In this submission VisionCare Devices is submitting two new models of vitreous cutter. The first model is the UniVit™ HE, which stands for Universal Vitcutter High Efficiency. The UniVit HE is offered in gauge sizes of 20, 23, 25, and 27). The UniVit™ HE™ operates up to 11,000 CPM depending upon vitrectomy system selection.			

UniVit™ HE (Universal Vitcutter High Efficiency)

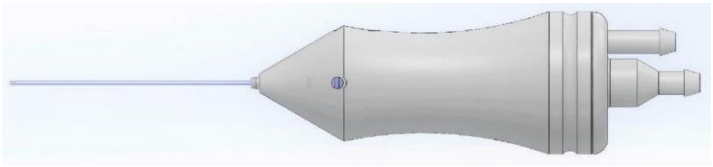


UniVit™ HE Base Model Numbers and Descriptions

Model No.	Product Name/Description
HE-20	*UniVit™ HE 20 Gauge, Single Outer Cutting Port*
HE-23	*UniVit™ HE 23 Gauge, Single Outer Cutting Port*
HE-25	*UniVit™ HE 25 Gauge, Single Outer Cutting Port*
HE-27	*UniVit™ HE 27 Gauge, Single Outer Cutting Port*

The second model offered, in this submission, is the UniVit™ UHS™, which stands for Universal Vitcutter Ultra High Speed. The UniVit UHS is offered gauge sizes of 23, 25, and 27. The UniVit operates up to 11,000 CPM depending upon vitrectomy system selection. The inner cutter has a port cut into it which allows for cutting forward and backwards; this in effect doubles the cut rate to 22,000 CPM.

UniVit™ UHS (Universal Vitcutter Ultra High Speed)



UniVit™ UHS Base Model Numbers and Descriptions

Model No.	Product Name/Description
UHS-23	*UniVit™ UHS 23 Gauge, Single Outer Cutting Port, Inner Cutter with a Cutting Port*
UHS-25	*UniVit™ UHS 25 Gauge, Single Outer Cutting Port, Inner Cutter with a Cutting Port*
UHS-27	*UniVit™ UHS 27 Gauge, Single Outer Cutting Port, Inner Cutter with a Cutting Port*

INDICATIONS FOR USE	
Intended Use as required per 21 CFR 807.92(a)(5)	
The UniVit™ HE and UniVit™ UHS are single use (disposable) products intended for use in both anterior and posterior segment (vitrectomy) ophthalmic surgeries when used with a pneumatically-driven vitrectomy system or phacoemulsification system that has a pneumatically-driven vitrectomy module.	
Comparison of Intended Uses for Subject Device and Predicate	
Name	**Indications for Use/Intended Use**
UniVit™ HE and UniVit™ UHS ***Subject Device***	UniVit™ HE and UniVit™ UHS are single use (disposable) products intended for use in both anterior and posterior segment (vitrectomy) ophthalmic surgeries when used with a pneumatically-driven vitrectomy system or phacoemulsification system that has a pneumatically-driven vitrectomy module.
K120170 ProCare HSP ***Predicate***	The VCD HSP Vitcutter and Accessories is a single use (disposable) product intended for use in both anterior and posterior segment (vitrectomy) ophthalmic surgeries when used with a pneumatically-driven vitrectomy system or phacoemulsification system that has a pneumatically-driven vitrectomy module. The VCD UniVit™ HE and UniVit™ UHS product has been sterilized by gamma radiation.

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE			
Device	**Current Submission**		**Primary Predicate**
	UniVit™ HE	**UniVit™ UHS**	**ProCare Plus HSP**
Aspiration Channel	Through the cutter tubing cannula	Identical	Identical
Patient Contact Material	Stainless Steel	Identical	Identical
Overall length of probe (nominal)	3.3 inches	Identical	Identical
Single-use/Reusable	Single use only	Identical	Identical
Shelf-life	3 Years	Identical	Identical
Sterile product packaging	Tyvek pouch	Identical	Identical
Sterility Method	Gamma	Identical	Identical
Connector	Connectors for pneumatic lines. Leuer connectors for aspiration line	Identical	Identical
Handpiece Material	ABS	Identical	Identical
Tubing Set	Polypropylene	Identical	Identical
Power Source for cutter activation	Pneumatic Pressure Pulse	Identical	Identical
Cutting Action Format	Guillotine	Identical	Identical
Cutter Return Mechanism	Spring	Spring	Spring

Differences	
Item of Comparison	**Description/Rationale**
Handpiece	Ergonomic Changes
Needle	Addition of 25 and 27 gauge options
Back cap	Color coded back cap to denote gauge size.
Inner Cutter	Added a cutting port to UniVit UHS Inner Cutter
Inner Cutter	Added coating to inner cutter to reduce friction UniVit HE and UniVit UHS

Cutting Speed	Increased cutting speed to 8K for UniVit HE
Cutting Speed	Increased cutting speed to 11K for UniVit UHS

Substantial Equivalence Summary

Operational and technological characteristics form the basis for the determination of substantial equivalence of the UniVit™ HE and UniVit™ UHS with the legally marketed predicate devices (K120170). The UniVit™ HE and UniVit™ UHS is substantially equivalent to the predicate devices.

PERFORMANCE DATA Summaries

Non-Clinical Tests – Harmonized Standards

The UniVit HE and the UniVit UHS have passed all safety tests for demonstrated compliance with the harmonized standards below.

Standard	Device Conforms	Results
ISO 10993-1	Biological evaluation of medical devices. Part 1: Evaluation and testing within a risk management process	Pass
ISO 10993-5	Biological evaluation of medical devices Part 5: Tests for in vitro cytotoxicity	Pass
ISO 10993-10	Biological evaluation of medical devices Part 10: Tests for irritation and skin sensitization	Pass
ISO 11137-1	Sterilization of health care products - Radiation - Part 1: Requirements for development, validation, and routine control of a sterilization process for medical devices [Including: Amendment 1 (2013)]	Pass
ISO 11137-2	Sterilization of health care products - Radiation - Part 2: Establishing the sterilization dose	Pass
ISO 11137-3	Sterilization of health care products - Radiation - Part 3: Guidance on dosimetric aspects of development, validation, and routine control	Pass

Deviations and Exclusions

Standard	Type	Deviation	Exclusions
ISO 10993-1	Biological evaluation of medical devices. Part 1: Evaluation and testing within a risk management process	None	None
ISO 10993-5	Biological evaluation of medical devices Part 5: Tests for in vitro cytotoxicity	None	None
ISO 10993-10	Biological evaluation of medical devices Part 10: Tests for irritation and skin sensitization	None	None
ISO 11137-1	Sterilization of health care products - Radiation - Part 1: Requirements for development, validation, and routine control of a sterilization process for medical devices [Including: Amendment 1 (2013)]	None	None
ISO 11137-2	Sterilization of health care products - Radiation - Part 2: Establishing the sterilization dose	None	None
ISO 11137-3	Sterilization of health care products - Radiation - Part 3: Guidance on dosimetric aspects of development, validation and routine control	None	None

Non-Clinical Bench Test Summary Reports

UniVit Needle Deformation – UniVit HE/UHS Outer Cutter (Needle)

VisionCare Devices validated the vitrectors deformation or bending of the outer needle to find out how much bend the outer needle can withstand before the outer needle fractures. The UniVit vitrector produced by VCD and the outer cutter attached to the vitrector did not fracture or break in normal operational circumstances. All gauge sizes were tested: 20, 23, 25, and 27. All tests passed without deviation.

UniVit Diaphragm Burst – UniVit HE/UHS

The UniVit HE/UHS vitrector models must not allow pressure to escape the needle port at any point during operation. The testing was done in an extreme vitrector operational configuration. The worst-case configuration for the vitrector with a compromised diaphragm and an overpressure condition. The handpieces performed as designed and did not allow pressure to exit the port area of the needle during a diaphragm breach or fail event. The testing was done using a final finished device. Only one gauge of handpiece was required for testing due to the UniVit vitrector family internal operation. The internal operation is identical in regards to axial inner-cutter functionality. All tests passed without deviation.

UniVit Fluidics – UniVit HE/UHS

The UniVit HE/UHS vitrector models were tested utilizing (2) rabbit eyes. The rabbit eyes were dissected and the vitreous was removed. Close examination of the retina was done during the vitreous evacuation to ensure no spikes or pulling forces on the retina occur. Aspiration flow was evaluated for metal flaking. The posterior vitreous removal performed on rabbit eyes provided no evidence or damage to the ocular structures in particular the retina of the rabbit eye, other than the incision site. Additionally, there was no evidence of tissue damage from heat and no evidence of metal flaking within the collected samples. All tests passed without deviation.

UniVit Metal Flaking – UniVit HE/UHS

The UniVit HE/UHS vitrector models must not generate metal flaking at any point during operation. The testing will be done in an extreme vitrector operational configuration. The worst-case operating configuration for the vitrector is running at high speed. VCD will run the vitrector at the highest cuts per minute for 30 minutes. The aspirated fluid will run through a .45 micron filter and the filter will be analyzed for metal flaking at 400x magnification. The vitrector functioned as designed regarding metal flaking during vitreous removal. This shows that the vitrector does not shed of flake metal inside the eye and will not adversely affect the patient. The testing was done on a finished device. All tests passed without deviation.

UniVit Tip Temperature – UniVit HE/UHS

The UniVit HE/UHS vitrector models must not exceed 104˚F at any point during operation. The testing will be done running the vitrector at 11,000 cuts per minute, in air. The vitrector was ran in a worse case condition without lubrication in air at 11,000 cpm to ensure needle does not exceed 104 ˚F. The vitrector outer cutter needle functioned as designed regarding tip temperature. The temperature on the outer cutter needle did not reach an excessive or unsafe temperature at any time during the testing. All tests passed without deviation.

UniVit Vibrational Testing – UniVit HE/UHS

The UniVit HE/UHS vitrector models must not exceed 2.5m/S² at any point during operation. The testing will be done in an extreme vitrector operational configuration. The worst-case operating configuration for the vitrector is running at high speed without lubrication. VCD ran the vitrector up to the highest CPM possible to record the vibration data. The UniVit vitrector functioned with very low vibration from 500 to 11,000 cuts per minute. The UniVit vitrector as tested on the finished product was well below the vibration levels according to current handheld tool standards. The UniVit vitrector was also lower in vibration frequency than the competitor model (reference device: DORC EVA under K190875) that was similar in design, operation, and needle gauge as the UniVit under test. All tests passed without deviation.

Clinical Studies

The UniVit™ HE™ and the UniVit UHS™, like the predicate device, did not require clinical trials.

FDA recognized standards, FDA guidance documents, harmonized standards, verification and validation, usability validation, and risk management activities have taken place for the UniVit™ HE and UniVit™ UHS

Conclusions

The UniVit™ HE™ and the UniVit UHS™ vitrectomy cutters were found to be substantially equivalent to the predicate device, demonstrated by performance testing and device comparisons. The UniVit™ HE™ and the UniVit UHS™ vitrectomy cutters share identical indications for use, similar design features and functional features with, and thus are substantially equivalent to, the predicate device.