June 21, 2024

Alcon Laboratories, Inc.
Ganesh Balachandar
Regulatory Affairs Manager
6201 South Freeway
Fort Worth, Texas 76134

Re: K233876
Trade/Device Name: UNITY VCS (8065000296); UNITY CS (8065000297)
Regulation Number: 21 CFR 886.4670
Regulation Name: Phacofragmentation system
Regulatory Class: Class II
Product Code: HQC, HQE, HQF
Dated: May 17, 2024
Received: May 20, 2024

Dear Ganesh Balachandar:

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,

Claudine H. Krawczyk -S

Claudine Krawczyk
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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K233876

Device Name
UNITY VCS (8065000296) ;
UNITY CS (8065000297)

Indications for Use *(Describe)*

UNITY VCS

The UNITY VCS console, when used with compatible devices, is indicated for use during anterior segment (i.e. phacoemulsification and removal of cataracts) and posterior segment (i.e. vitreoretinal) ophthalmic surgery.

In addition, with the optional laser this system is indicated for photocoagulation (i.e. vitreoretinal and macular pathologies), iridotomy, and trabeculoplasty procedures.

UNITY CS

The UNITY CS console, when used with compatible devices, is indicated for use during anterior segment (i.e. phacoemulsification and removal of cataracts) ophthalmic surgery.

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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In accordance with 21 CFR 807.92, Alcon hereby provides the 510(k) summary for the UNITY VCS and UNITY CS.

1. SUBMITTER

Applicant	Alcon Laboratories, Inc. 6201 South Freeway Fort Worth, TX 76134-2099
Primary Correspondent	Ganesh Balachandar, M.S. Regulatory Affairs Manager Alcon Research LLC, on behalf of Alcon Laboratories, Inc. 20511 Lake Forest Drive Lake Forest, CA 92630-7741 +1 (949) 322-5101 ganesh.balachandar@alcon.com
Secondary Correspondent	Ophelia Biggs Director, Regulatory Affairs Alcon Research LLC, on behalf of Alcon Laboratories, Inc. 20511 Lake Forest Drive Lake Forest, CA 92630-7741 +1 (949) 217-3854 ophelia.biggs@alcon.com
Date Prepared	June 21, 2024

2. SUBJECT DEVICES

Device Trade Name	UNITY VCS (8065000296); UNITY CS (8065000297)
Classification Number and Name (Product Code in Parentheses)	*For UNITY VCS*: • 21 CFR 886.4150, Vitreous aspiration and cutting instrument (HQE) • 21 CFR 886.4670, Phacofragmentation system (HQC) • 21 CFR 886.4690, Ophthalmic laser (HQF) *For UNITY CS*: • 21 CFR 886.4670, Phacofragmentation system (HQC)
Regulatory Class	II

3. PREDICATE DEVICES

FOR UNITY VCS:	
Predicate Device	CONSTELLATION Vision System
510(k) Number	K141065
Classification Number and Name (Product Code in Parentheses)	• 21 CFR 886.4150, Vitreous aspiration and cutting instrument (HQE) • 21 CFR 886.4670, Phacofragmentation system (HQC)
Regulatory Class	II

FOR UNITY VCS (Laser Functionality):	
Predicate Device	Next-Generation Laser
510(k) Number	K062624
Classification Number and Name (Product Code in Parentheses)	• 21 CFR 886.4390, Laser, Ophthalmic (HQF)
Regulatory Class	II

FOR UNITY CS:	
Predicate Device	CENTURION Vision System with Active Sentry
510(k) Number	K161794
Classification	21 CFR 886.4670, Phacofragmentation system (HQC)

Number and Name (Product Code in Parentheses)	
Regulatory Class	II

4. DEVICE DESCRIPTION

The UNITY VCS is a multifunctional surgical instrument for use in anterior and posterior segment ophthalmic surgeries. The capabilities of the UNITY VCS include driving a variety of handpieces that provide the ability to cut vitreous and tissues, emulsify the crystalline lens, illuminate the posterior segment of the eye, and apply diathermy to stop bleeding. Flow-controlled or vacuum-controlled aspiration is used to remove ocular matter from the eye. Pressure-controlled irrigation/infusion capability is provided to replace fluid in the eye and enters the eye directly through either an infusion cannula or a handpiece. The graphical user interface is menu-driven. The operator provides inputs using the touchscreen panel, the remote control, and the foot controllers.

An optional, fully integrated laser module is available that can be installed in the base of the UNITY VCS configuration for vitreoretinal surgery. The laser delivers the same visible 532-nm green treatment beam designed for ophthalmic use as in the predicate device.

When used with compatible components and accessories, the system will perform anterior and posterior segment ophthalmic procedures, including irrigation/aspiration, phacoemulsification, extraction, vitrectomy, diathermy coagulation, intraocular illumination, photocoagulation, viscous fluid control, tissue grabbing and cutting.

The UNITY CS is a multifunctional surgical instrument for use in anterior segment ophthalmic surgeries. The capabilities of the UNITY CS include driving a variety of handpieces that provide the ability to cut anterior vitreous and tissues, emulsify the crystalline lens, and apply diathermy to stop bleeding. Flow-controlled or pressure-controlled aspiration is used to remove ocular matter from the eye. Pressure-controlled irrigation/infusion capability is provided to replace fluid in the eye and enters the eye directly through either an infusion cannula or a handpiece. The graphical user interface is menu-driven, and the operator provides inputs using the touchscreen panel, the remote control, and the foot controllers.

When used with compatible components and accessories, the system will perform anterior segment ophthalmic procedures, including irrigation/aspiration, phacoemulsification, extraction, vitrectomy, and diathermy coagulation.

The UNITY VCS and UNITY CS are intended to be used within a clinic(s)/hospital(s)/surgical practice network.

Both devices are for prescription use only.

5. INDICATIONS FOR USE

UNITY VCS:

The UNITY VCS console, when used with compatible devices, is indicated for use during anterior segment (i.e. phacoemulsification and removal of cataracts) and posterior segment (i.e.

vitreoretinal) ophthalmic surgery.

In addition, with the optional laser this system is indicated for photocoagulation (i.e. vitreoretinal and macular pathologies), iridotomy and trabeculoplasty procedures.

UNITY CS:

The UNITY CS console, when used with compatible devices, is indicated for use during anterior segment (i.e. phacoemulsification and removal of cataracts) ophthalmic surgery.

6. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS TO PREDICATE

Characteristic	CONSTELLATION Vision System (Predicate Device for Subject Device 1)	UNITY VCS (Subject Device 1)	CENTURION Vision System with Active Sentry (Predicate Device for Subject Device 2)	UNITY CS (Subject Device 2)
Administrative				
510(k)	K141065	K233876	K161794	K233876
Intended Use	Anterior and posterior segment ophthalmic surgery	Same (The subject device, consisting of the console and compatible devices, is intended to facilitate management of fluid and gases, as well as removal, grasping, cutting, illumination, and coagulation of ocular materials)[1]	Anterior segment ophthalmic surgery	Same (The subject device, consisting of the console and compatible devices, is intended to facilitate management of fluid as well as removal, cutting, and coagulation of ocular materials)[1]
Indications for Use	The CONSTELLATION® Vision System is indicated for the following: The CONSTELLATION® Vision System is an ophthalmic microsurgical system that is indicated for both anterior segment (i.e. phacoemulsification and	The UNITY VCS console, when used with compatible devices, is indicated for use during anterior segment (i.e. phacoemulsification and removal of cataracts) and posterior segment (i.e. vitreoretinal) ophthalmic	The Centurion Vision System is indicated for emulsification, separation, irrigation, and aspiration of cataracts, residual cortical material and lens epithelial cells, vitreous aspiration and cutting associated with anterior	The UNITY CS console, when used with compatible devices, is indicated for use during anterior segment (i.e. phacoemulsification and removal of cataracts) ophthalmic surgery.

[1] The proposed language for the subject devices' Intended Use statements are in parentheses, and is a more specific manner of describing the medical purpose of the subject devices. Despite the difference in wording, the essence remains the same between the language in parentheses and the intended use language of the predicate devices (anterior and posterior segment ophthalmic surgery), because the actions of fluid and gas management, removal, grasping, cutting, illumination, and coagulation of ocular materials can occur only during anterior or posterior segment ophthalmic surgery.

Characteristic	CONSTELLATION Vision System (Predicate Device for Subject Device 1)	UNITY VCS (Subject Device 1)	CENTURION Vision System with Active Sentry (Predicate Device for Subject Device 2)	UNITY CS (Subject Device 2)
	removal of cataracts) and posterior segment (i.e., vitreoretinal) ophthalmic surgery in addition to the indications included with the optional Next-Generation laser. The AutoSert® IOL Injector Handpiece is intended to deliver qualified ACRYSOF® intraocular lenses into the eye following cataract removal. The AutoSert® IOL Injector Handpiece achieves the functionality of injection of intraocular lenses. The AutoSert is indicated for use with ACRYSOF® lenses SN60WF, SN6AD1, SN6AT3 through SN6AT9, as well as approved ACRYSOF® lenses that are specifically indicated for use with this inserter, as indicated in the	surgery. In addition, with the optional laser this system is indicated for photocoagulation (i.e. vitreoretinal and macular pathologies), iridotomy and trabeculoplasty procedures.[2]	vitrectomy, bipolar coagulation, and intraocular lens injection. The AutoSert IOL Injector Handpiece is intended to deliver qualified AcrySof intraocular lenses into the eye following cataract removal. The AutoSert IOL Injector Handpiece achieves the functionality of injection of intraocular lenses. The AutoSert IOL Injector Handpiece is indicated for use with the AcrySof lenses SN60WF, SNWAD1, SN6AT3 through SN6AT9, as well as approved AcrySof lenses that are specifically indicated for use with this inserter, as indicated in the approved labeling of those lenses.	

[2] The laser functionality of UNITY VCS is substantially equivalent to Alcon's Next-Generation Laser (K062624), cleared November 2007.

Characteristic	CONSTELLATION Vision System (Predicate Device for Subject Device 1)	UNITY VCS (Subject Device 1)	CENTURION Vision System with Active Sentry (Predicate Device for Subject Device 2)	UNITY CS (Subject Device 2)
	approved labeling of those lenses.			
Console Features				
Monolith	Yes	Yes	Yes	Yes
Tray	Yes	Yes	Yes	Yes
Touch Panel Display	Yes	Yes	Yes	Yes
RFID for accessory connections	Yes	Yes	No	Yes
e-Connectivity	Yes	Yes	Yes	Yes
User Interface	Touch panel display, foot controllers, remote control	Same	Same	Same
Electrical Power Specifications	100-240 V AC, 50/60 Hz	Same	Same	Same
Operating Temperature Range	10 – 35°C	Same	Same	Same
Console Height, Width and Depth	Height: 62.4” Width: 30.3” Depth: 36”	Height: 64.6” Width: 25.4” Depth:28.3”	Height:64.6” Width:19.6’ Depth:31.6”	Height: 64.6” Width: 25.4” Depth:28.3”
Maximum Humidity (RH = Relative Humidity)	95% RH non-condensing	Same	Same	Same
Fluidics Features				
Push Prime	Yes	Yes	No	Yes
Infusion/Irrigation Source Change	Yes	Yes	Yes	Yes
Aspiration Pressure Control	Yes	Yes	Yes	Yes
Aspiration Flow Control	Yes	Yes	Yes	Yes

Characteristic	CONSTELLATION Vision System (Predicate Device for Subject Device 1)	UNITY VCS (Subject Device 1)	CENTURION Vision System with Active Sentry (Predicate Device for Subject Device 2)	UNITY CS (Subject Device 2)
Suction Flow Control	Yes	Yes	No	No
Flow Control – Irrigation	No	Yes	Yes	Yes
Flow Control – Infusion	No	Yes	No	No
IOP-Controlled Infusion/Irrigation	Yes	Yes	Yes	Yes
Pressurized Infusion	Yes	Yes	No	No
Pressurized Irrigation	Yes	Yes	Yes	Yes
Proportional Reflux	Yes	Yes	No	Yes
Continuous Reflux	Yes	Yes	Yes	Yes
Micro Reflux	Yes	Yes	No	Yes
Pneumatics Features				
Anterior Vitrectomy	Yes	Yes	Yes	Yes
Posterior Vitrectomy	Yes	Yes	No	No
Proportional Forceps	Yes	Yes	No	No
Proportional Scissors	Yes	Yes	No	No
Multi-Cut Scissors	Yes	Yes	No	No
VFC Inject	Yes	Yes	No	No
VFC Extract	Yes	Yes	No	No
Fluid-Air Exchange	Yes	Yes	No	No
Auto-Gas Filling	Yes	No	No	No
Ultrasound Features				
Longitudinal Phaco	Yes	Yes	Yes	Yes
Longitudinal Frag	Yes	Yes	No	No
Torsional Phaco	Yes	Yes	Yes	Yes

Characteristic	CONSTELLATION Vision System (Predicate Device for Subject Device 1)	UNITY VCS (Subject Device 1)	CENTURION Vision System with Active Sentry (Predicate Device for Subject Device 2)	UNITY CS (Subject Device 2)
Torsional Frag	No	Yes	No	No
Active Sentry Phaco	No	Yes	Yes	Yes
4D Phaco	No	Yes	No	Yes
Diathermy Features				
Frequency	1.5 MHz	Same	Same	Same
Rated Load	75 Ω	Same	Same	Same
Maximum Power	10 W	Same	Same	Same
Illumination Features				
Illumination source	Xenon Bulb	RGB LED	None	None
Number of Simultaneous Outputs	2	3	None	None
Illumination Color	Fixed	Adjustable	None	None
Laser Features				
Therapeutic laser wavelength	532 nm	Same	No	No
Single-spot power output range	30 mW to 2 W	Same	No	No
Laser Indirect Ophthalmoscope support	Yes	Yes	No	No
Includes Multi-Spot Laser Probe (MSLP)	No	Yes	No	No
Integrated Illumination (MSLP only)	No	Yes	No	No
FMS and Accessory Device Packs				
Single-Use	Yes	Yes	Yes	Yes

Characteristic	CONSTELLATION Vision System (Predicate Device for Subject Device 1)	UNITY VCS (Subject Device 1)	CENTURION Vision System with Active Sentry (Predicate Device for Subject Device 2)	UNITY CS (Subject Device 2)
Sterilization method	Ethylene Oxide	Same	Same	Same
Includes Anterior Pack	Yes	Yes	Yes	Yes
Includes Posterior Pack	Yes	Yes	No	No
Includes Combination Pack	Yes	Yes	No	No
Surgical Suite Integration				
NGENUITY 3D Visualization System	Yes	Yes	Yes	Yes
LuxOR microscope	No	Yes	Yes	Yes
Verion Image Guided System	No	Yes	Yes	Yes

7. SUMMARY OF STUDIES

7.1 Non-Clinical Testing

Biocompatibility

The UNITY VCS and UNITY CS consoles are not intended to have patient contact. The materials used for the device consoles are common and widely used for ophthalmic and similar applications without reported heath concerns. Per ISO 10993-1, no further biocompatibility testing is required.

Alcon conducted biocompatibility testing on the patient-contacting accessories and met ISO 10993 requirements for chemical characterization, cytotoxicity, sensitization, irritation, and acute systemic toxicity. Packaging materials passed cytotoxicity requirements from ISO 11607-1 and ASTM F2475.

Sterilization and Shelf Life

The UNITY VCS and CS system consoles are provided non-sterile and are not intended to be sterilized during routine use. The system consoles are intended for use with sterile accessories.

Alcon performed sterilization testing on the accessories provided sterile to the user. Test results passed the predetermined acceptance criteria and met the appropriate sterilization standards.

Shelf life testing on the sterile accessories yielded successful test results for the latest pull point for the consumable accessories covered by this premarket notification.

Electromagnetic Compatibility (EMC)/ Wireless / Electrical Safety

Alcon assessed the EMC, wireless, and electrical / mechanical safety of the UNITY VCS and UNITY CS according to IEC 60601-1, IEC 60601-1-2, IEC 60601-1-6, IEC 60601-2-2, and IEC 60601-4-2, and the final FDA guidance documents "*Electromagnetic Compatibility (EMC) of Medical Devices*," issued June 6, 2022, and "*Radio Frequency Wireless Technology in Medical Devices*," issued on August 14, 2013. The subject devices met all requirements from the aforementioned standards and followed FDA recommendations where applicable from said guidance documents.

Software

Alcon developed and tested the UNITY VCS and UNITY CS device software functions according to ANSI / AAMI / IEC 62304, "*Medical Device Software – Software Life Cycle Processes*" and internal Alcon procedures that follow this standard. Premarket submission documentation was prepared in accordance with the final FDA guidance "*Content of Premarket Submissions for Device Software Functions*," issued on June 14, 2023. Testing met all requirements from IEC 62304, and all FDA recommendations for documentation were met.

Alcon also fulfilled FDA's cybersecurity recommendations for the subject devices in accordance

with the final FDA guidance "*Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions*," dated September 2023.

Performance Testing

Alcon conducted performance tests on the UNITY VCS and UNITY CS devices to demonstrate safety, effectiveness, and substantial equivalence to predicate devices, in accordance with IEC 80601-2-58.

Safety tests of the UNITY VCS and UNITY CS demonstrated the compliance of the subject devices to the appropriate standards. Biocompatibility evaluations of materials coming into contact with the patient or patient fluid path demonstrated compliance with the appropriate standard from the ISO 10993 series or with ISO 16671:2015.

Sterile, single-use UNITY VCS and UNITY CS accessories have been shown to be sterilizable to a sterility assurance level (SAL) of 10^{-6}, and the sterilization process for these accessories has been validated per the required standard.

Technological characteristics affecting clinical performance are similar to those of the predicate devices previously listed. Like the predicate devices, the subject devices have been developed and manufactured in compliance with 21 CFR 820 and ISO 14971. Non-clinical testing noted above has demonstrated that the functional requirements have been met and that the subject devices are equivalent to the predicate devices.

7.2 Animal/Clinical Testing

The risk assessment for the subject devices did not require any animal or clinical testing as mitigation against any identified risks.

8. CONCLUSION

The subject devices share the same intended use as the predicate devices. Their indications for use are equivalent with each other. The technological characteristics affecting clinical performance are similar to those of the predicate devices previously listed. Risk profiles are equivalent between the subject devices and the predicate devices. The predicate devices and the subject devices have been developed and manufactured in compliance with 21 CFR 820 and ISO 14971. Non-clinical testing noted above demonstrated that the functional requirements were met, and that the subject devices are equivalent to the predicate devices.

Therefore, the UNITY VCS and UNITY CS are deemed substantially equivalent to their predicate devices, the CONSTELLATION Vision System, Alcon Next-Generation Laser (for the UNITY VCS laser functionality), and the CENTURION Vision System, respectively.