December 3, 2021

Bausch + Lomb, Incorporated
Heather Christie
Sr. Specialist, Regulatory Affairs
3365 Tree Court Industrial Boulevard
St. Louis, MO 63122

Re: K211786
Trade/Device Name: Independent Corneal Viewing Chamber (IVC-21)
Regulatory Class: Unclassified
Product Code: LYX
Dated: October 5, 2021
Received: October 8, 2021

Dear Heather Christie:

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,

for Tieuvi Nguyen, Ph.D.
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)*
K211786

Device Name
Independent Viewing Chamber (IVC-21)

Indications for Use *(Describe)*
The Independent Viewing Chamber (IVC-21) is a sterile container that may be used for the transportation of corneal tissue preserved in Optisol GS storage media.

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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K211786 510(k) Summary: Independent Viewing Chamber (IVC-21)

I. Submitter	Bausch & Lomb Inc. 3365 Tree Court Industrial Blvd. St. Louis MO 63122 General Telephone: 636-226-3017
Contact	*Heather Christie, (585) 356-5422, heather.christie@bausch.com*
Date Prepared	June 1, 2021. Date revised October 1 2021. Date revised version S001 October 18, 2021. Date revised version November 29, 2021
II. Device	
Name of Device	Independent Viewing Chamber (IVC-21) – K211786
Common Name	Media, Corneal Storage
Classification Name	None
Regulatory Class	Unclassified
Product Code	LYX
Regulation Number	None
III. Predicate Device	Independent Viewing Chamber (IVC-12) – K921729

IV. Device Description

The Independent Corneal Viewing Chamber (IVC) is a sterile container (consisting of a jar, lid, and o-ring) that may be used for transportation of corneal tissue preserved in Optisol GS storage media.

V. Indications for Use

The IVC is a sterile container that may be used for the transportation of corneal tissue preserved in Optisol GS storage media.

VI. Comparison of Technological Characteristics with the Predicate

The Independent Viewing Chamber (IVC-21) subject of the premarket notification is a larger version of the currently cleared IVC-12 predicate device (cleared via K921729 under Chiron which was later acquired by Bausch + Lomb). The IVC-21 contains a lid, jar, and o-ring.

	IVC-21 (subject device)	**IVC-12 (K921729)**	**Comment**
Indications for Use	The Independent Corneal Viewing Chamber (IVC) is a sterile container that may be used for the transportation of corneal tissue preserved in Optisol GS storage media.	The Independent Corneal Viewing Chamber (IVC) is a sterile container that may be used for the transportation of corneal tissue preserved in storage media.	Added specific storage media name to IVC-21 IFU

Sterility	Gamma	Same	No difference
Shelf Life	18 months	12 months	Increased shelf life - Refer Shelf Life section for detailed discussion
Lid	0.64” high 1.96" diameter	0.56” high 1.96" diameter	Slight height difference
O-ring	Silbione LSR 4360 silicone with 3% Nusil Med 1-4900-7 (Blue)	60 Durometer Silicone Red: Siloprene LSR 2060	Base material changed from a non-medical grade silicone and colorant (predicate) to a medical grade silicone and colorant (subject device)
Jar	1.95" wide 1.76" high	1.95” wide 1.76" high	No difference
Jar pedestal configuration	9 pedestal elements in circular configuration	12 pedestal elements in circular configuration	Reduction of pedestal elements in subject device allowing more spacing for better viewing
Lid viewing diameter	1.14" diameter	1.06" diameter	Larger viewing diameter in subject device
Sterile Barrier Configuration	HIPS pre-formed blister tray with Tyvek lid stock	Tyvek pouch	Changed from pouch to tray packaging configuration
Sterile Barrier Component Materials	Blister Tray: 0.030 thick virgin white HIPS Tyvek lid stock: Dupont Grade – 1073B Spunbonded Polyolefin	Pouch: Tyvek Web = Dupont Grade 1073B; Film Web = Laminated 48 PET/200 LDPE	IVC-21 uses a HIPS blister tray which is commonly used on other Bausch + Lomb surgical products Same Tyvek Dupont Grade 1073B used between IVC-12 and IVC-21
Sterility	Gamma	Same *Note: initial Chiron 510k noted EtO sterilization however, Bausch + Lomb records show this has always been gamma sterilized	No difference
Minimum Sterilization Dose	25 kGy	Same	No difference

Packaging Configuration	Quantity 1 IVC-21 placed in blister tray and sealed with Tyvek lid stock	Quantity 1 IVC-12 wrapped in cloth wrap with latex free cohesive tape and sealed in Tyvek pouch	Refer packaging images below

VII.
Performance Data

The IVC-21 container passes all functional and simulated use testing with no failures or anomalies noted. Based on the attached results of the container as designed, passes all of the design input requirements.

Biocompatibility assessment

The device is an external communicating device with prolonged contact with tissue. Biocompatibility assessment for the IVC-21 has been performed in accordance with the requirements of ISO 10993-1 and FDA guidance "Use of International Standard ISO 10993-1, 'Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process". Test results satisfied the acceptance criteria as defined by the associated ISO 10993-1 standards. The jar component of the device was determined to be substantial equivalent to the jar component of the predicate device based on material characterization, suppliers, and manufacturing processes.

The lid and O-ring were tested jointly for sensitization, ocular irritation, and cytotoxicity.

Sensitization summary:

The test article, IVC-21 Independent Viewing Chamber (gamma sterilized), was evaluated for the potential to cause delayed dermal contact sensitization in a guinea pig maximization test. This study was conducted based on the requirements of ISO 10993-10, Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization. The test article was extracted in 0.9% sodium chloride USP and sesame oil, NF. Each extract was intradermally injected and occlusively patched to ten test guinea pigs (per extract). The extraction vehicle was similarly injected and occlusively patched to five control guinea pigs (per vehicle). Following a recovery period, the test and control animals received a challenge patch of the appropriate test article extract and the vehicle control. All sites were scored for dermal reactions at 24 and 48 hours after patch removal. The test article extracts showed no evidence of causing delayed dermal contact sensitization in the guinea pig. The test article was not considered a sensitizer in the guinea pig maximization test.

Irritation summary:

The test article, IVC-21 Independent Viewing Chamber (gamma sterilized), was extracted in balanced salt solution and evaluated for the potential to cause intraocular irritation or toxicity following an intracameral (anterior chamber) injection in rabbits. In one eye of each of six animals, 0.15 mL of aqueous fluid was evacuated from the anterior chamber and replaced with 0.15 mL of the test article extract. The opposite eye of each animal received a similar injection of balanced salt solution and served as the control. The eyes were evaluated for irritation by slit-lamp examination daily for three days. There were no significant differences in ocular observations between eyes treated with the test article extract and those treated with the control vehicle. The test article extract was not irritating to intraocular tissues.

Cytotoxicity summary:

The test article, IVC-21 Independent Viewing Chamber (gamma sterilized), was evaluated for potential cytotoxic effects using an in vitro mammalian cell culture test. This study was

conducted following the guidelines of ISO 10993-5, Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity. A single preparation of the test article was extracted in single strength Minimum Essential Medium (1X MEM) at 37°C for 24 hours. The negative control, reagent control, and positive control were similarly extracted. Triplicate monolayers of L-929 mouse fibroblast cells were dosed with each extract and incubated at 37□C in the presence of 5% CO2 for 48 hours. Following incubation, the monolayers were examined microscopically for abnormal cell morphology and cellular degeneration. The test article extract showed no evidence of causing cell lysis or toxicity. The test article extract met the requirements of the test since the grade was less than a grade 2 (mild reactivity).

Systemic toxicity, genotoxicity, and material mediated pyrogenicity were assessed by chemical characterization and analytical chemistry.

Limulus Amebocyte Lysate (LAL) testing [Endotoxin]
Per the Nelson Laboratories test report, IVC-21 passed the BET testing. The measured EU level was lower than the acceptance criterion of 0.2 EU/device prescribed in "Endotoxin Testing Recommendations for Single-Use Intraocular Ophthalmic Devices, Guidance for Industry and Food and Drug Administration Staff," August 17, 2015. Based on these test results, IVC-21 is not likely to result in Toxic Anterior Segment Syndrome (TASS).

Electrical safety and electromagnetic compatibility (EMC)
Not applicable for this device

Software Verification and Validation Testing
Not applicable for this device

Mechanical and acoustic testing
Not applicable for this device

Animal Study
Not applicable for this device

Non-Clinical Performance Data
Functional verification testing and simulated use validation testing was successfully performed. The IVC-21 container used for testing was production equivalent. The product was gamma sterilized prior to the functional testing.

All tests executed for the Functional Verification Testing (Group 1) and Simulated Use Validation (Group 2) passed all requirements. The IVC-21 container passes all functional and simulated use testing with no failures or anomalies noted. Based on the attached results, the IVC-21 meets or exceeds all of the design input requirements.

Clinical Studies
Not applicable for this device

VIII. Conclusion

The modifications proposed in this 510(k) Premarket Notification did not impact the conformance to applicable standards specific to this device. Any differences between the predicate and proposed devices do not affect the substantial equivalence of the device as demonstrated by the performance testing.