October 9, 2025

Ophtecs Corporation
% Bret Andre
Principal Consultant
Andre Vision and Device Research
6119 Canter Lane
West Linn, OR 97068

Re: K251876
Trade/Device Name: cleadew GP hydra one
Regulation Number: 21 CFR 886.5918
Regulation Name: Rigid Gas Permeable Contact Lens Care Products
Regulatory Class: Class II
Product Code: MRC
Dated: June 10, 2025
Received: September 9, 2025

Dear Bret Andre:

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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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,

J Angelo Green -S

J. Angelo Green, Ph.D.
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

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)*

K251876

Device Name

cleadew GP hydra one

Indications for Use *(Describe)*

cleadew GP hydra one is indicated for cleaning, removing protein, rinsing, disinfecting, conditioning, and storing fluoro silicone acrylate and silicone acrylate rigid gas permeable contact lenses.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

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510 (k) SUMMARY

This 510(k) summary is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is: K251876

I. SUBMITTER

Date Prepared: June 10, 2025

Name: **OPHTECS CORPORATION**
Address: 5-2-4, Minatojima-minamimachi, Chuo-Ku,
Kobe, Hyogo, 650-0047. Japan

Contact Person: Joe Yoneda
CEO & Representative Director
Phone number: +81 355210030

Consultant: Bret Andre
Andre Vision and Device Research
6119 Canter Ln.
West Linn, OR 97068
Phone number: (503) 372-5226

II. DEVICE

Trade Name: **cleadew GP hydra one**

Common Name: Multi-purpose Contact Lens Care Solution

Classification Name: Rigid Gas Permeable Contact Lens Care Products (21 CFR 886.5918)

Regulatory Class: Class II

Product Code: MRC

III. PREDICATE DEVICE

The cleadew GP hydra one is substantially equivalent in terms of actions, indications, and technological characteristics to the following predicate devices:

- "Boston SIMPLUS Multi-Action Solution"
  By Bausch + Lomb
  510(k) number: K181627
  Device Classification: II
  Product Code: MRC

IV. DEVICE DESCRIPTION

Ophtecs cleadew GP hydra one is a sterile, aqueous, buffered solution that contains Boric acid, Disodium Phosphate, Trometamol, Glutamic Acid, Sodium Chloride, Polyoxyethylene 9 Lauryl Ether, Tetrasodium (1-hydroxy-1,1-ethanediyl)bis(phosphonate), C12-13 Alkyl Glyceryl Hydrolyzed Hyaluronate, Sodium Hyaluronate and Hypromellose; preserved with Hydrogen peroxide (0.004%) and Polyhexamethylene biguanide hydrochloride (0.0005%). The solution is for cleaning, removing protein, rinsing, disinfecting, conditioning, and storing fluoro silicone acrylate and silicone acrylate rigid gas permeable contact lenses.

V. INDICATIONS FOR USE

cleadew GP hydra one is indicated for cleaning, removing protein, rinsing, disinfecting, conditioning, and storing fluoro silicone acrylate and silicone acrylate rigid gas permeable contact lenses.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH PREDICATE DEVICE

cleadew GP hydra one is substantially equivalent to the Boston SIMPLUS Multi-Action Solution predicate device (K181627) in terms of the following:

- Intended use
- Indications for use
- Actions
- Classification – Rigid Gas Permeable Contact Lens Care Products (21 CFR 886.5918)
- How supplied (sterile, multi dose)
- Contains preservatives

The following matrix illustrates the intended use and other characteristics of the cleadew GP hydra one, as well as the predicate device.

	OPHTECS CORPORATION **cleadew GP hydra one**	**Bausch + Lomb** **Boston SIMPLUS Multi-Action Solution**
		Predicate Device (K181627)
Indication for Use	cleadew GP hydra one is indicated for cleaning, removing protein, rinsing, disinfecting, conditioning, and storing fluoro silicone acrylate and silicone acrylate rigid gas permeable contact lenses.	Bausch + Lomb Boston Simplus Multi-Action Solution is indicated for cleaning, removing protein, rinsing, disinfecting, conditioning, storing and cushioning fluoro silicone acrylate and silicone acrylate rigid gas permeable contact lenses.
Classification	21 CFR 886.5918	21 CFR 886.5918
Product Code	MRC	MRC
Class	Class II	Class II
Volume	360 mL; 60 mL	105 mL; 30 mL
Sterility	Supplied Sterile	Supplied Sterile
Container	Tamper Resistant White Plastic Bottle	Tamper Resistant White Plastic Bottle
Ingredients	Boric acid, Disodium Phosphate, Trometamol, Glutamic Acid, Sodium Chloride, Polyoxyethylene 9 Lauryl Ether, Tetrasodium (1-hydroxy-1,1-ethanediyl)bis(phosphonate), C12-13 Alkyl Glyceryl Hydrolyzed Hyaluronate, Sodium Hyaluronate and Hypromellose; preserved with Hydrogen peroxide (0.004%) and Polyhexamethylene biguanide hydrochloride (0.0005%)	poloxamine, hydroxyalkylphosphonate, boric acid, sodium borate, sodium chloride, hydroxypropylmethyl cellulose, and Glucam; preserved with chlorhexidine gluconate (0.003%), polyaminopropyl biguanide (0.0005%)

VII. PERFORMANCE DATA

~ Non-Clinical Studies ~

A series of studies were completed to demonstrate the substantial equivalence of the cleadew GP hydra one to the predicate device. Results of non-clinical testing are summarized below:

Biocompatibility

Biocompatibility testing on the cleadew GP hydra one was conducted in accordance with Good Laboratory Practices (GLP) and the results confirmed the following:

- cleadew GP hydra one is non-cytotoxic, non-ocular irritating, non-sensitizing, and does not show oral or acute systemic toxicity
- Extracts from cleadew GP hydra one packaging components and lens case are non-cytotoxic, non-ocular irritating, and does not show acute systemic toxicity

Microbiology

A series of studies were performed to demonstrate the microbiological efficacy and discard date for cleadew GP hydra one. Results demonstrated that the formulation meets the criteria for disinfection and preservative efficacy. Ophtecs cleadew GP hydra one met the requirements of the disinfecting regimen procedure for the fluoro silicone acrylate and silicone acrylate rigid gas permeable contact lens materials tested.

Lens Compatibility

Compatibility studies of cleadew GP hydra one were conducted in accordance with ISO 11981:2017 with fluoro silicone acrylate and silicone acrylate rigid gas permeable contact lenses. Results demonstrate that cleadew GP hydra one is physically compatible with rigid gas permeable contact lenses.

Extractable Testing:

Testing was conducted in accordance with ISO 18369-4:2017 to evaluate the effect of cleadew GP hydra one on the quantity of extractables from fluoro silicone acrylate and silicone acrylate rigid gas permeable contact lens materials. The cleadew GP hydra one did not affect the amount of extractables observed from the materials.

Preservative Uptake:

Testing was conducted in accordance with ISO 11986:2017 to evaluate the uptake of PHMB from cleadew GP hydra one in fluoro silicone acrylate and silicone acrylate rigid gas permeable contact lens materials. For both materials uptake of PHMB from cleadew GP hydra was not observed.

Cleaning

Studies were conducted to demonstrate the cleaning efficacy of cleadew GP hydra one with rigid gas permeable (RGP) lenses. The following cleaning studies were conducted:

- Protein Cleaning Efficacy: The results of the study demonstrates the cleaning efficacy of cleadew GP hydra one against undenatured proteins adhering to rigid gas permeable contact lens.
- Critical Micelle Concentration (CMC): The cleaning efficacy of cleadew GP hydra one was evaluated through the determination of CMC. The surfactant concentration in the formulation was determined to exceed the CMC value.

Stability

Stability studies were conducted to confirm the finished specifications and sterility of cleadew GP hydra one remains stable throughout the proposed expiration date.

~ Clinical Studies ~

OPHTECS CORPORATION conducted a 3-month, double-masked, bilateral, randomized, clinical trial to compare the clinical performance of two rigid gas permeable (RGP) multi-purpose solutions and test whether cleadew GP Hydra one (Test) is substantially equivalent to Boston SIMPLUS (Control) when used with a rub and rinse regimen.

One-hundred and one (101) existing RGP contact lens wearers were enrolled onto the study, 97 of whom were dispensed study lenses. In total, 66 were randomized to the test group and 31 to the control group. Of the 97 dispensed subjects, 70% were female. Mean age at baseline was 63.5 ±9.4 years (range: 41–82 years). The mean spherical refraction was -3.69 D (range: 6.00 to -10.00 D) and mean refractive cylinder was -0.78 D (range: 0 to -2.00 D). In total, 91 subjects (94%, 91/97) completed the study: 61 (92%) test subjects and 30 (97%) control subjects.

The following conclusions are supported by the findings of this study:

- The incidence of ocular adverse events with Cleadew GP Hydra one was non-inferior to that with Boston SIMPLUS™.
- The average grades for slip-lamp assessments of limbal hyperemia, bulbar hyperemia, corneal vascularization, and corneal staining with Cleadew GP Hydra one were non-inferior to those with Boston SIMPLUS™.
- The average grades for subjective comfort, lens deposits, and wettability with Cleadew GP Hydra one were non-inferior to those with Boston SIMPLUS™.

The results of the study support a substantial equivalence determination.

VIII. CONCLUSIONS

Substantial Equivalence

Based on the results of the clinical and non-clinical testing presented in this Premarket Notification, the cleadew GP hydra one is as safe and effective as the predicate device when used in accordance with the labeled directions for use and for the proposed indication.