August 13, 2026

Menicon Co., Ltd.
% Bret Andre
Consultant
Andre Vision and Device Research
6119 Canter Lane
West Linn, Oregon 97068

Re: K253795
Trade/Device Name: MeniSept 3% Hydrogen Peroxide Cleaning & Disinfecting Solution
Regulation Number: 21 CFR 886.5928
Regulation Name: Soft (Hydrophilic) Contact Lens Care Products
Regulatory Class: Class II
Product Code: LPN, MRC
Dated: October 21, 2025
Received: July 14, 2026

Dear Mr. 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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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

Enclosure

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K253795

Please provide the device trade name(s).

MeniSept 3% Hydrogen Peroxide Cleaning & Disinfecting Solution

Please provide your Indications for Use below.

MeniSept 3% Hydrogen Peroxide Cleaning & Disinfecting Solution is indicated for use in cleaning, daily protein removal, disinfection, and storing of soft (hydrophilic) contact lenses (including silicone hydrogel lenses) and rigid gas permeable (fluoro silicone acrylate and silicone acrylate) contact lenses, as recommended by your eye care professional.

Please select the types of uses (select one or both, as applicable).

- ☐ Prescription Use (Part 21 CFR 801 Subpart D)
- ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

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: K253795

I. SUBMITTER

Date Prepared:	October 21, 2025
Name:	**Menicon Co., Ltd.**
Address:	21-19, Aoi 3, Naka-ku, Nagoya, Aichi 460-0006 JAPAN
Contact Person:	Kana Nagasaki Regulatory Affairs
Phone number:	81-52-9351676
Consultant:	Bret Andre Andre Vision and Device Research 6119 Canter Ln. West Linn, OR 97068
Phone number:	(503) 372-5226

II. DEVICE

Trade Name:	MeniSept 3% Hydrogen Peroxide Cleaning & Disinfecting Solution
Classification Name:	Soft (hydrophilic) Contact Lens Care Product (21 CFR 886.5928) Rigid Gas Permeable Contact Lens Care Product (21 CFR 886.5918)
Regulatory Class:	Class II
Product Code:	LPN, MRC
Reason for Submission:	Change in supplier for lens case; Change in trade name

III. PREDICATE DEVICE

The MeniSept 3% Hydrogen Peroxide Cleaning & Disinfecting Solution is substantially equivalent in terms of actions, indications, and technological characteristics to the following predicate device:

- "Menicon 3% Hydrogen Peroxide Cleaning & Disinfecting Solution"
  By Menicon Co., Ltd.
  510(k) number: K191872
  Device Classification: II
  Product Code: LPN, MRC

IV. DEVICE DESCRIPTION

The MeniSept 3% Hydrogen Peroxide Cleaning & Disinfecting Solution system consists of: MeniSept 3% Hydrogen Peroxide Cleaning & Disinfecting Solution and the special lens case. The lens case consists of a transparent cup and a lens holder-lens case cap assembly with a neutralizer catalyst disk. MeniSept 3% Hydrogen Peroxide Cleaning & Disinfecting Solution and the special lens case must always be used together.

The preservative free, aqueous MeniSept 3% Hydrogen Peroxide Cleaning & Disinfecting Solution contains: hydrogen peroxide 3%, phosphonic acid compound (stabilizer), citric acid, polyethylene glycol, sodium chloride, sodium hydroxide, and phosphate (buffer system).

V. INDICATIONS FOR USE

MeniSept 3% Hydrogen Peroxide Cleaning & Disinfecting Solution is indicated for use in cleaning, daily protein removal, disinfection, and storing of soft (hydrophilic) contact lenses (including silicone hydrogel lenses) and rigid gas permeable (fluoro silicone acrylate and silicone acrylate) contact lenses, as recommended by your eye care professional.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH PREDICATE DEVICE

This 510(k) application seeks to add a new lens case supplier for the MeniSept 3% Hydrogen Peroxide Cleaning & Disinfecting Solution. No other changes have been made; the solution and neutralizer remains identical to the predicate device (K191872).

The following matrix illustrates the intended use and other characteristics of the MeniSept 3% Hydrogen Peroxide Cleaning & Disinfecting Solution, as well as the predicate device.

	Menicon Co., Ltd. **MeniSept 3% Hydrogen Peroxide Cleaning & Disinfecting Solution** (Subject Device)	**Menicon Co., Ltd.** **Menicon 3% Hydrogen Peroxide Cleaning & Disinfecting Solution** Predicate Device (K191872)
Indication for Use	MeniSept 3% Hydrogen Peroxide Cleaning & Disinfecting Solution is indicated for use in cleaning, daily protein removal, disinfection, and storing of soft (hydrophilic) contact lenses including silicone hydrogel lenses) and rigid gas permeable (fluoro silicone acrylate and silicone acrylate) contact lenses, as recommended by your eye care professional.	Menicon 3% Hydrogen Peroxide Cleaning & Disinfecting Solution is indicated for use in cleaning, daily protein removal, disinfection, and storing of soft (hydrophilic) contact lenses including silicone hydrogel lenses) and rigid gas permeable (fluoro silicone acrylate and silicone acrylate) contact lenses, as recommended by your eye care professional.
Classification	Soft (hydrophilic) Contact Lens Care Product (21 CFR 886.5928) Rigid Gas Permeable Contact Lens Care Product (21 CFR 886.5918)	Soft (hydrophilic) Contact Lens Care Product (21 CFR 886.5928) Rigid Gas Permeable Contact Lens Care Product (21 CFR 886.5918)
Product Code	LPN, MRC	LPN, MRC
Class	Class II	Class II
Lens Case Design	specially designed lens case with neutralizing disk (added different supplier from K191872)	specially designed lens case with neutralizing disk
Minimum Disinfection Time	6 hours	6 hours
Color of Bottle Cap	red	red
Tamper Resistant	Yes	yes

VII. PERFORMANCE DATA

~ Non-Clinical Studies ~

A series of studies were completed to demonstrate the substantial equivalence of the MeniSept 3% Hydrogen Peroxide Cleaning & Disinfecting Solution to the predicate device. Lens compatibility, cleaning efficacy, and biocompatiblity studies on the solution and neutralization disc were addressed in K191872 and are applicable to the subject device.

Results of non-clinical testing on the modified device are summarized below:

Biocompatibility

Biocompatibility testing on the lens case cup, cap, and lens holders for MeniSept 3% Hydrogen Peroxide Cleaning & Disinfecting Solution was conducted in accordance with Good Laboratory Practices (GLP). Testing was done per applicable ISO standards (cytotoxicity (ISO 10993-5), acute ocular irritation (ISO 10993-23), and acute systemic toxicity (ISO 10993-11)). The results confirm the extracts from the lens case components are non-cytotoxic, non-ocular irritating, and do not show acute systemic toxicity.

Neutralization Profile

Tests were conducted to evaluate the effectiveness of the neutralization lens case of the MeniSept 3% Hydrogen Peroxide Cleaning & Disinfecting Solution in terms of residual hydrogen peroxide level. The MeniSept 3% Hydrogen Peroxide Cleaning & Disinfecting Solution showed a similar neutralization profile to the predicate device.

Disinfecting and Preservative Efficacy

Disinfecting efficacy test was conducted to evaluate the antimicrobial activity of the MeniSept 3% Hydrogen Peroxide Cleaning & Disinfecting Solution as a contact lens disinfection product. Results demonstrated that harmful microorganisms were effectively reduced to an ISO level at 1.5, 3, 4.5, and 6 hours after neutralization.

~ *Clinical Studies* ~

Clinical studies were unnecessary for this application.

VIII. CONCLUSIONS

Substantial Equivalence

Based on the results of the testing presented in this Premarket Notification, MeniSept 3% Hydrogen Peroxide Cleaning & Disinfecting Solution is as safe and effective as the predicate device when used in accordance with the labeled directions for use and for the proposed indication.