March 2, 2020

Menicon Co., Ltd.
Li Haosheng, Ph.D.
International Regulatory Affairs
Menicon Co., Ltd.
3-21-19, Aoi, Naka-ku,
Nagoya, 460-0006 JAPAN

Re: K191872
Trade/Device Name: Menicon 3% Hydrogen Peroxide Cleaning and 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: January 29, 2020
Received: February 3, 2020

Dear Dr. Li Haosheng:

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,

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K191872

Device Name

Menicon 3 % Hydrogen Peroxide Cleaning & Disinfecting Solution

Indications for Use *(Describe)*

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.

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

Menicon 3% Hydrogen Peroxide Cleaning & Disinfecting Solution

1. Applicant Information

Menicon Co., Ltd.
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JAPAN

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Date Prepared:	July 10, 2019

2. Device Information

Device classification:	Class II
Classification name:	21 CFR 886.5928 Soft (hydrophilic) Contact Lens Care Product 21 CFR 886.5918 Rigid Gas Permeable Contact Lens Care Product
Product code:	LPN, MRC
Proprietary name:	Menicon 3% Hydrogen Peroxide Cleaning & Disinfecting Solution

3. Predicate Device

Menicon claims substantial equivalence to K142284 Clear Care Plus Cleaning & Disinfecting Solution and K030522 Clear Care Cleaning & Disinfecting Solution.

4. Description of Device

The Menicon 3% Hydrogen Peroxide Cleaning & Disinfecting Solution system consists of: Menicon 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. Menicon 3% Hydrogen Peroxide Cleaning & Disinfecting Solution and the special lens case must always be used together.

The preservative free, aqueous Menicon 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).

5. Indications for Use

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.

6. Performance Data

Non-Clinical Data

A series of preclinical tests were performed to demonstrate the substantial equivalence of the Menicon 3% Hydrogen Peroxide Cleaning & Disinfecting Solution to the predicate devices. All tests were conducted in accordance with the *Premarket Notification 510(k) Guidance Document for Contact Lens Care Products (1997)* or according to valid scientific protocols.

- **Lens Compatibility**
  Compatibility testing was conducted with six commercially available hydrogel and silicone hydrogel soft contact lenses: **Acuvue2** (etafilcon A), **Acuvue Oasys** (senofilcon A), **Biofinity** (comfilcon A), **Air Optix Aqua** (lotrafilcon B), **Definitive74** (efrofilcon A) and **PureVision2** (balafilcon A), and 2 commercially available RGP lenses: **Menicon Z** (tisilfocon A) and **Boston IV** (itafocon B). Results demonstrated that the Menicon 3% Hydrogen Peroxide Cleaning & Disinfecting Solution was compatible with the test contact lenses.

- **Neutralization Profile**
  Tests were conducted to evaluate the effectiveness of the neutralization lens case of the Menicon 3% Hydrogen Peroxide Cleaning & Disinfecting Solution in terms of residual hydrogen peroxide level. The Menicon 3% Hydrogen Peroxide Cleaning & Disinfecting Solution showed a similar neutralization profile to the predicate device. In addition, stability of the neutralizer catalyst disk was confirmed for 90-cycles treatments.

- **Disinfecting and Preservative Efficacy**
  Disinfecting efficacy test was conducted to evaluate the antimicrobial activity of the Menicon 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 6 and 24 hours and 7 days after neutralization. In addition, Preservative Efficacy test was conducted to ensure 3-month open bottle discard date of the Menicon 3% Hydrogen Peroxide Cleaning & Disinfecting Solution.

- **Cleaning Efficacy**
  Studies were conducted in an *in-vitro* system to quantify the ability of the Menicon 3% Hydrogen Peroxide Cleaning & Disinfecting Solution to remove proteins and lipids from commercially available hydrogel and silicone hydrogel soft contact lenses and RGP lenses, and to compare its performance to the predicate device. Results suggested that both solutions performed similarly in the removal of lens deposition.

- **Toxicology**
  A series of *in-vitro* and *in-vivo* biocompatibility tests were conducted in accordance with the GLP regulation (21 CFR Part 58) to ensure the safety of the Menicon 3% Hydrogen Peroxide Cleaning & Disinfecting Solution. Results demonstrated that the neutralized solution, the lens case materials and the neutralizer catalyst were non-toxic and non-irritating under the experimental conditions.

Clinical Data

Clinical studies were unnecessary for this application.

Conclusion

Based upon the data presented, the Menicon 3% Hydrogen Peroxide Cleaning & Disinfecting Solution is as safe, as effective and performs as well as the predicate devices.

7. Substantial equivalence

The claim of substantial equivalence to the previously cleared devices is supported by the following Comparison of Characteristics in Table 1.

Table 1 Comparison of Characteristics

	Menicon 3% Hydrogen Peroxide Cleaning & Disinfecting Solution	**Clear Care Plus**	**Clear Care**
510(k) Number	New	K142284	K030522
Product Codes	LPN, MRC	LPN, MRC	LPN
Indications for Use	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.	Indicated for use in simultaneous 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.	Indicated for use in simultaneous cleaning, daily protein removal, disinfecting, and storing of soft (hydrophilic) contact lenses (including silicone hydrogel lenses) contact lenses as recommended by your eye care practitioner.
Lens Case Design	specially designed lens case with neutralizing disk	specially designed lens case with neutralizing disk	specially designed lens case with neutralizing disk
Minimum Disinfection Time	6 hours	6 hours	6 hours
Color of Bottle Cap	red	red	red
Tamper Resistant	yes	yes	yes