DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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August 28, 2015

Menicon Co., Ltd.
% Ms. Ellen M. Beucler
Vice President
Foresight Regulatory Strategies, Inc.
187 Ballardvale Street, Suite 180
Wilmington, MA 01887

Re: K151768
Trade/Device Name: Menicon Saline Rinse Solution
Regulation Number: 21 CFR 886.5928
Regulation Name: Soft (Hydrophilic) Contact Lens Care Products
Regulatory Class: Class II
Product Code: LPN, MRC
Dated: June 30, 2015
Received: June 30, 2015

Dear Ms. Beucler:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Kesia Y. Alexander -A

for Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K151768

Device Name
Menicon Saline Rinse Solution

Indications for Use *(Describe)*
The Menicon Saline Rinse Solution is indicated for use following proper lens disinfection as recommended by the eye care practitioner. The Menicon Saline Rinse Solution is for rinsing soft (hydrophilic), rigid gas permeable and hard contact lenses prior to lens insertion. This solution may also be used as an insertion solution for large diameter (scleral) contact lenses, as a rinse for contact lens cases, and may be used as needed throughout the day to rinse 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.

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K 151768

510(k) Summary

MENICON SALINE RINSE SOLUTION

1. Applicant Information

Menicon Co., Ltd.
21-19, Aoi 3-Chome, Naka-ku
Nagoya 460-0006
Japan

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Date Prepared:	July 8, 2015

2. Device Information

Classification name:	Contact Lens Care Products
Device classification:	Class II
Regulation number:	21 CFR 886.5918 (Rigid Gas Permeable Contact Lens Care Products) 21 CFR 886.5928 (Soft (hydrophilic) Contact Lens Care Products)
Product code:	LPN
Proprietary name:	Menicon Saline Rinse Solution

3. Predicate Devices

Menicon Co., Ltd. claims substantial equivalence to K093367, Cachet Pharmaceuticals Pvt. Ltd. Sterile Saline Solution and K110221, Optics Laboratory, Inc. Eye-Cept Sterile Saline Solution.

4. Description of Device

The Menicon Saline Rinse Solution is a sterile unit dose non-preserved, 0.9% NaCl (normal saline) solution indicated for rinsing soft (hydrophilic), rigid gas permeable (RGP) and hard contact lenses prior to insertion. The rinsing solution removes debris and bacteria following proper disinfection as recommended by the eye care practitioner.

This sterile, normal saline solution can be used to rinse contact lens cases, rinse lenses as needed throughout the day and to fill the concave posterior surface of scleral lenses prior to insertion to provide a more natural environment than currently approved multipurpose solutions which contain preservatives and osmolarity agents that are not designed to be held against the cornea for extended periods of time.

5. Indications for Use

The Menicon Saline Rinse Solution is indicated for use following proper lens disinfection as recommended by the eye care practitioner. The Menicon Saline Rinse Solution is for rinsing soft (hydrophilic), rigid gas permeable and hard contact lenses prior to lens insertion. This solution may also be used as an insertion solution for large diameter (scleral) contact lenses, as a rinse for contact lens cases, and may be used as needed throughout the day to rinse contact lenses.

6. Performance Data

Non-Clinical Data

Biocompatibility tests were unnecessary for this application. The solution is a 0.9 % saline solution that meets the requirements of USP saline therefore testing was not required. The components are safe for the intended use.

Clinical Data

Clinical studies involving the saline rinse solution were unnecessary for this application. Lens care solutions used with this Saline Rinse Solution are already cleared for use as cleaning, rinsing, disinfection and storage solutions for contact lenses.

Conclusion

Based upon the composition of the saline rinse solution and previous test data presented, the Menicon Saline Rinse Solution is as safe, as effective and performs as well as the predicate devices. A comparison of the new device and the predicate devices is presented in Table 1.

7. Substantial Equivalence

The claim of substantial equivalence to the previously cleared to K093367, Cachet Pharmaceuticals Pvt. Ltd Sterile Saline Solution and K110221, Optics Laboratory, Inc. Eye-Cept Sterile Saline Solution, is supported by the following Comparison of Characteristics in Table 1.

The Menicon Saline Rinse Solution and the predicates are similar in composition and intended use. Therefore, Menicon Saline Rinse Solution is substantially equivalent to the predicate device.

Table 1 Comparison of Characteristics

	Menicon Saline Rinse Solution	**Cachet Pharmaceuticals Sterile Saline Solution**	**Optics Laboratory Inc. Eye-Cept Sterile Saline Solution**
Device Name	Contact Lens Care Product	Contact Lens Care Product	Contact Lens Care Product
Trade Name	Menicon Saline Rinse Solution	Sterile Saline Solution	Eye-Cept Sterile Saline Solution
Document Number	K151768	K093367	K110221
Classification	Ophthalmic	Ophthalmic	Ophthalmic
Product Code	LPN	LPN	LPN
Regulation Number	21 CFR 886.5918 21 CFR 886.5928	21 CFR 886.5928	21 CFR 886.5928
Class	II	II	II
Intended Use	For use following proper lens disinfection as recommended by the eye care practitioner. The Menicon Saline Rinse Solution is for rinsing soft (hydrophilic), rigid gas permeable and hard contact lenses prior to lens insertion. This solution may also be used as an insertion solution for large diameter (scleral) contact lenses, as a rinse for contact lens cases, and may be used as needed throughout the day to rinse contact lenses.	For rinsing and wetting of soft (hydrophilic) contact lenses	For rinsing soft contact lenses after cleaning and for wetting soft contact lenses after disinfection before use.
Volume	5 mL	-	10 mL
Preservative Free	yes	yes	yes
Container Usage	single use	single use	single use
Sterility	Sterile	Sterile	Sterile
Materials	Plastic resin container with twist off cap	Plastic resin container with twist off cap	Plastic resin container with twist off cap
Biocompatibility	Components used in this lens case have been evaluated in accordance with Part 10993 of the ISO standard for Biological Evaluation and the FDA Guidance for Contact Lens Care Products	Components used for this product have been evaluated in accordance with FDA Guidance for Contact Lens Care Products	Components used for this product have been evaluated in accordance with FDA Guidance for Contact Lens Care Products