November 16, 2017

Menicon Co., Ltd.
% Ellen Beucler
Vice President
Foresight Regulatory Strategies, Inc.
187 Ballardvale Street, Suite A250
Wilmington, MA 01887

Re: K173136
Trade/Device Name: Menicon Progent Protein Remover for Rigid Gas Permeable Contact Lenses
Regulation Number: 21 CFR 886.5918
Regulation Name: Rigid Gas Permeable Contact Lens Care Products
Regulatory Class: Class II
Product Code: MRC
Dated: September 28, 2017
Received: September 29, 2017

Dear Ellen 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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Denise L. Hampton -S

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K173136

Device Name

Menicon Progent Protein Remover

Indications for Use *(Describe)*

Menicon Progent Protein Remover for Rigid Gas Permeable Contact Lenses, when used as directed, cleans and removes protein deposits from fluorosilicone 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.

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510(k) Summary

Menicon Progent Protein Remover for Rigid Gas Permeable Contact Lenses

1. Applicant Information

Menicon Co., Ltd.
Contact Person: Kenichi Tanaka
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E-mail: kenichi-tanaka@menicon.co.jp
Date Prepared: November 7, 2017

2. Device Information

Proprietary name:	Menicon Progent Protein Remover
Device classification:	Class II
Common Name:	RGP Contact Lens Care Product
Classification name:	RGP Contact Lens Care Product
Regulation number:	21 CFR 886.5918
Product code:	MRC

3. Predicate Devices

The predicate devices are the RGP contact lens cleaners, Boston Cleaner (P860029) and Boston Advance Cleaner (K923437 and K974466). These products are sold over the counter without prescription.

4. Description of Device

Menicon Progent Protein Remover for Rigid Gas Permeable Contact Lenses is the mixture of two sterile solutions, Progent A (active ingredient, sodium hypochlorite) and Progent B (active ingredient, potassium bromide). Progent A and B are mixed in a Progent Vial. Menicon Rinse solution is used once the lens soaking cycle is complete. The Progent treatment is recommended every two weeks. The frequency may vary according to the condition of your lens. Follow your eye care professional's directions (to a maximum of every 5 days).

5. Indications for Use

Menicon Progent Protein Remover for Rigid Gas Permeable Contact Lenses, when used as directed, cleans and removes protein deposits from fluorosilicone acrylate RGP contact lenses.

6. Performance Data

Non-Clinical Data

Non-clinical studies were unnecessary for this application. Menicon Progent Protein Remover has been cleared in prior applications. There are no product formulation changes made in this application therefor no non-clinical studies were required.

Clinical Data

Clinical studies were unnecessary for this application. Menicon Progent Protein Remover has been cleared in prior applications. There are no product formulation changes made in this application therefor no clinical studies were required.

Conclusion

Based upon the product history and data presented, the Menicon Progent Protein Remover can be used as safely and as effectively as the Boston Cleaner and the Boston Advance Cleaner.

7. Substantial Equivalence

The claim of substantial equivalence to the previously approved Boston Cleaner and cleared Boston Advance Cleaner for rigid gas permeable contact lenses is based on the fact that both products are contact lens cleaners for rigid gas permeable contact lenses and when used as directed, can be used safely and effectively to remove protein deposits from the surface of rigid contact lens materials.

Table 1

Device Comparison

	Menicon Progent	**Boston Cleaner**	**Boston Advance**
Product Code	MRC	LPN, MRC	LPN, MRC
Class	II	II	II
Regulation Number	21 CFR 886.5918	21 CFR 886.5918	21 CFR 886.5918
Action	Cleans and removes protein deposits from contact lenses	Cleans and removes deposits from contact lenses	Cleans and removes deposits from contact lenses
Indicated for	RGP Contact Lenses	RGP Contact Lenses	RGP Contact Lenses
Primary Container	Plastic resin container with twist off cap	Plastic resin container with screw cap	Plastic resin container with screw cap
Container	Single Use	Multi Use	Multi Use
Sterile	Yes	Yes	Yes