

510(k) Summary

JUL 03 2013

**MENICON UNIQUE pH MULTI-PURPOSE SOLUTION
FOR RIGID GAS PERMEABLE CONTACT LENSES**

1. Applicant Information

Menicon Co., Ltd.
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JAPAN
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Date Prepared: April 19, 2013

2. Device Information

Classification name: Rigid gas permeable contact lens care products
Device classification: Class II
Regulation number: 21 CFR, Subpart F, Section 886.5918
Product code: MRC
Proprietary name: Menicon Unique pH Multi-Purpose Solution for Rigid Gas Permeable Contact Lenses

3. Predicate Devices

Menicon claims substantial equivalence to Alcon RGP Multi-Purpose Solution ID 100136 for Rigid Gas Permeable Contact Lenses previously cleared under K000148 on April 11, 2000.

4. Description of Device

Menicon Unique pH Multi-Purpose Solution is a sterile, buffered aqueous solution. It contains hydroxypropyl guar, polyethylene glycol, poloxamine, boric acid, propylene glycol, and is preserve with polyquaternium-1 0.0011%, and edetate disodium 0.01%.

5. Indications for Use

Menicon Unique pH Multi-Purpose Solution is indicated for the cleaning, rinsing, disinfection and conditioning of fluorosilicone acrylate and silicone acrylate rigid gas permeable contact lenses.

6. Performance Data

Non Clinical Data

In support of the Alcon Laboratories RGP Multi-Purpose Solution ID 100136 cleared in K000148, a complete set of testing (preclinical, biocompatibility and container tests) was completed to establish the safety and efficacy of the solution.

Testing conducted on the new device consisted of evaluating the solution manufactured in the Japanese facility. Testing included chemical analysis of the Japanese product to confirm equivalence to the product manufactured by Alcon, container biocompatibility tests and shelf life stability tests.

Clinical Data

The safety and efficacy of this solution has been clinically evaluated in the cleared Alcon Laboratories 510(k) application, Alcon RGP Multipurpose Solution K000148.

This application is for the same formulation with the alternate brand name, Menicon Unique pH Multi-Purpose Solution, which will be manufactured in Japan by Menicon Nect. The new device and the predicate device have the same composition, ingredients and intended use. Based upon this fact there were no additional clinical studies required to establish the safety and efficacy of the new device.

Conclusion

Based upon the test data presented, the Menicon Unique pH Multi-Purpose Solution for Rigid Gas Permeable Contact Lenses is as safe, as effective and performs as well as the predicate device. A comparison of the new device and the predicate device is presented in Table 1.

7. Substantial Equivalence

Menicon Co., Ltd claims that the Menicon Unique pH Multi-Purpose Solution for Rigid Gas Permeable Contact Lenses is substantially equivalent to the predicate device, Alcon RGP Multi-Purpose Solution ID 100136 for Rigid Gas Permeable Contact Lenses previously cleared under K000148.

The claim of substantial equivalence is made based upon product testing and the fact that the solutions are the same formulation, are manufactured by equivalent manufacturing processes and meet the same product release specifications.

Table 1 Comparison of Characteristics		
	New Device	Predicate Device
Manufacturer	Menicon Co., Ltd.	Alcon Laboratories
Device Name	Rigid Gas Permeable Contact Lens Care Product	Rigid Gas Permeable Contact Lens Care Product
Trade Name	Menicon Unique pH Multi-Purpose Solution	Alcon RGP Multi-Purpose Solution (ID 100136)
510(k)	K130805	K000148
Classification	Ophthalmic	Ophthalmic
Product Code	MRC	MRC
Regulation Number	21 CFR 886.5918	21 CFR 886.5918
Class	II	II
Intended Use	Menicon Unique pH Multi-Purpose Solution is indicated for the cleaning, rinsing, disinfection and conditioning of fluorosilicone acrylate and silicone acrylate rigid gas permeable contact lenses.	Alcon RGP Multi-Purpose Solution is indicated for the cleaning, rinsing, disinfection and conditioning of fluorosilicone acrylate and silicone acrylate rigid gas permeable contact lenses.
Composition	A sterile, buffered aqueous solution. It contains hydroxypropyl guar, polyethylene glycol, poloxamine, boric acid, propylene glycol, and is preserve with polyquaternium-1 0.0011%, and edetate disodium 0.01%.	A sterile, buffered aqueous solution. It contains hydroxypropyl guar, polyethylene glycol, poloxamine, boric acid, propylene glycol, and is preserve with polyquaternium-1 0.0011%, and edetate disodium 0.01%.
Biocompatibility	Components used in this product have been evaluated in accordance with Part 10993 of the ISO standard for Biological Evaluation. Test results indicate the test articles meet the ISO standard	Components used in this product have been evaluated in accordance with Part 10993 of the ISO standard for Biological Evaluation. Test results indicate the test articles meet the ISO standard



July 3, 2013

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - W066-G609
Silver Spring, MD 20993-002

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

Re: K130805
Trade/Device Name: Menicon Unique pH Multipurpose Solution
Regulation Number: 21 CFR 886.5918
Regulation Name: Rigid Gas Permeable Contact Lens Care Product
Regulatory Class: Class II
Product Code: MRC
Dated: April 19, 2013
Received: April 22, 2013

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 Small Manufacturers, International and Consumer Assistance 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 Small Manufacturers, International and Consumer Assistance 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 -S

for Malvina Eydelman, M.D.
Director
Division of Ophthalmic and
Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Menicon Co. Ltd.

Indications for Use

510(k) Number: K130805

Device Name: Menicon Unique pH Multi-Purpose Solution for Rigid Gas Permeable Contact Lenses

Indications for Use:

Menicon Unique pH Multi-Purpose Solution is indicated for the cleaning, rinsing, disinfection and conditioning of fluorosilicone acrylate and silicone acrylate rigid gas permeable contact lenses.

Prescription Use _____
(part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use XX
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE- CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Leonid Livshitz

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(Division Sign-Off)

Division of Ophthalmic and Ear, Nose, and Throat
Devices

510(k) Number: K130805

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