February 22, 2018

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

Re: K180004
Trade/Device Name: Menicon ASRB (asmofilcon A) Silicone Hydrogel Soft Contact Lens
Regulation Number: 21 CFR 886.5925
Regulation Name: Soft (Hydrophilic) Contact Lens
Regulatory Class: Class II
Product Code: LPL
Dated: January 2, 2018
Received: January 3, 2018

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,

Scott E. Steffen -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)*
K180004

Device Name

The Menicon ASRB (asmofilcon A) Silicone Hydrogel Soft Contact Lens

Indications for Use *(Describe)*

The Menicon ASRB (asmofilcon A) SPHERICAL Silicone Hydrogel Soft Contact Lens is indicated for daily wear frequent replacement for the optical correction of refractive ametropia (myopia and hyperopia) in aphakic and non-aphakic persons with non-diseased eyes who may have 1.50 D or less of astigmatism.

The Menicon ASRB (asmofilcon A) TORIC Silicone Hydrogel Soft Contact Lens is indicated for daily wear frequent replacement for the optical correction of refractive ametropia (myopia or hyperopia with astigmatism) in aphakic and non-aphakic persons with non-diseased eyes with 3.00 D or less of refractive astigmatism.

The Menicon ASRB (asmofilcon A) MULTIFOCAL Silicone Hydrogel Soft Contact Lens is indicated for daily wear frequent replacement for the optical correction of refractive ametropia (myopia and hyperopia) and emmetropia with presbyopia in aphakic and non-aphakic persons with non-diseased eyes who may require a reading addition of +3.00 D or less and who may have 1.50 D or less of astigmatism.

The Menicon ASRB (asmofilcon A) MULTIFOCAL TORIC Silicone Hydrogel Soft Contact Lens is indicated for daily wear frequent replacement for the optical correction of refractive ametropia (myopia and hyperopia with astigmatism) and presbyopia in aphakic and non-aphakic persons with non-diseased eyes who may require a reading addition of +3.00 D or less and who may have up to approximately 3.00 D or less of refractive astigmatism.

The Menicon ASRB (asmofilcon A) Silicone Hydrogel Soft Contact Lens is a frequent replacement lens. The lenses are intended to be worn on a daily wear basis with removal for cleaning and chemical disinfection (not heat) prior to reinsertion, as recommended by the eye care practitioner.

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.

510(k) Summary

Menicon ASRB (asmofilcon A)
Silicone Hydrogel Soft Contact Lens

1. Applicant Contact Information

Menicon Co., Ltd..
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JAPAN
Contact Person: Kenichi Tanaka
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Date Prepared: February 15, 2018

2. Device Information

Classification name:	Soft (hydrophilic) Contact Lens
Device classification:	Class II
Regulation number:	21 CFR 886.5925
Product code:	LPL
Proprietary name:	Menicon ASRB (asmofilcon A) Silicone Hydrogel Soft Contact Lens

3. Predicate Device

Menicon claims substantial equivalence to K073459 Alcon Air Optix Aqua (lotrafilcon B) Soft Contact Lens.

4. Description of Device

The Menicon ASRB (asmofilcon A) Silicone Hydrogel Soft Contact Lens is a hydrophilic contact lens which is available as a spherical/aspherical, toric, multifocal and multifocal toric lens. This soft contact lens is indicated for daily wear frequent replacement.

The non-ionic lens material (asmofilcon A) is a random co-polymer containing polydimethyl siloxane macromonomer. It consists of 60% asmofilcon A and 40% water by weight when immersed in a buffered saline solution. The lens is available with a pale blue visibility handling tint, C.I. Reactive Blue 246.

The hydrophilic material characteristics allow aqueous solutions to enter the lens. In its fully hydrated state, the lens is approximately 40% water by weight.

5. Indications for Use

The Menicon ASRB (asmofilcon A) SPHERICAL Silicone Hydrogel Soft Contact Lens is indicated for daily wear frequent replacement for the optical correction of refractive ametropia (myopia and hyperopia) in aphakic and non-aphakic persons with non-diseased eyes who may have 1.50 D or less of astigmatism.

The Menicon ASRB (asmofilcon A) TORIC Silicone Hydrogel Soft Contact Lens is indicated for daily wear frequent replacement for the optical correction of refractive ametropia (myopia or hyperopia with astigmatism) in aphakic and non-aphakic persons with non-diseased eyes with 3.00 D or less of refractive astigmatism.

The Menicon ASRB (asmofilcon A) MULTIFOCAL Silicone Hydrogel Soft Contact Lens is indicated for daily wear frequent replacement for the optical correction of refractive ametropia (myopia and hyperopia) and emmetropia with presbyopia in aphakic and non-aphakic persons with non-diseased eyes who may require a reading addition of +3.00 D or less and who may have 1.50 D or less of astigmatism.

The Menicon ASRB (asmofilcon A) MULTIFOCAL TORIC Silicone Hydrogel Soft Contact Lens is indicated for daily wear frequent replacement for the optical correction of refractive ametropia (myopia and hyperopia with astigmatism) and presbyopia in aphakic and

non-aphakic persons with non-diseased eyes who may require a reading addition of +3.00 D or less and who may have up to approximately 3.00 D or less of refractive astigmatism.

The Menicon ASRB (asmofilcon A) Silicone Hydrogel Soft Contact Lens is a frequent replacement lens. The lenses are intended to be worn on a daily wear basis with removal for cleaning and chemical disinfection (not heat) prior to reinsertion, as recommended by the eye care practitioner.

6. Performance Data

Non-Clinical Data

A series of *in-vitro* and *in-vivo* preclinical tests were performed to assess the safety and effectiveness of the Menicon ASRB (asmofilcon A) Silicone Hydrogel Soft Contact Lens. All tests were conducted in accordance with the GLP regulation (21 CFR Part 56) or according to valid scientific protocols.

The results of the biocompatibility testing and evaluation demonstrate that the lens material/extracts are non-toxic, non-irritating and non-sensitizing under the experimental conditions, and the material properties are consistent with the predicate lens.

Clinical Data

A three-month clinical study was completed to evaluate the safety and efficacy of the Menicon ASRB (asmofilcon A) Silicone Hydrogel Soft Contact Lens for daily wear, frequent replacement use.

The study evaluated ninety (90) male and female subjects who were randomized and dispensed lenses in a 2:1 ratio with 60 subjects dispensed into the Test lenses and 30 Subjects dispensed into the Control lenses. The primary outcome measures were biomicroscopy and adverse event rates along with lens visual acuity comparisons between the Test and the Control contact lenses. Secondary Outcome measures included average lens wearing times and subjective lens comfort assessed by frequency or symptoms.

The Test contact lens was found to be substantially equivalent to the Control contact lens for safety and efficacy.

Conclusion

Based upon the data presented, the Menicon ASRB (asmofilcon A) Soft Contact lens 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 ASRB	**Air Optix Aqua**
510(k)	To be assigned	K073459
USAN	asmofilcon A	lotrafilcon B
Product Code	LPL	LPL
Modality	Daily wear, Frequent replacement	Daily wear, Frequent replacement
FDA Lens Group	SiHy Class V	SiHy Class V
Device Classification	II	II
Manufacturing Method	Cast Molded	Cast Molded
Sterilization	Moist Heat	Moist Heat
Packaging	Blister Pack	Blister Pack
Packaging Solution	Phosphate Buffered Saline	Phosphate Buffered Saline
Visibility Tint	C.I. Reactive Blue #246	Phathalocyanine Blue
Light Transmittance	> 93 %	> 94 %
Water Content	40%	33%
Refractive Index	1.423	1.4217
DK $\times 10^{-11}$ $[(cm^2/sec) \times (mL\ O_2)/(mL \times mm\ Hg)]$	129	110
Powers	- 13.00 to +6.00 D	- 20.00 to +20.00 D
Diameter	13.0 to 18.0 mm	13.0 to 15.0 mm
Base Curve	8.0 to 9.0 mm	8.0 to 9.2 mm
Optical Design	Spherical, Aspherical, Toric, Multifocal, Multifocal Toric	Spherical, Aspherical, Toric, Multifocal, Multifocal Toric