Menicon Co., Ltd.
% Ellen Beucler
Vice President
Foresight Regulatory Strategies, Inc.
187 Ballardvale Street, Suite 250
Wilmington, MA 01887

Re: K180819
Trade/Device Name: One Day Flat Pack (hioxifilcon A) Daily Disposable Soft Contact Lens
Regulation Number: 21 CFR 886.5925
Regulation Name: Soft (Hydrophilic) Contact Lens
Regulatory Class: Class II
Product Code: LPL
Dated: March 28, 2018
Received: March 29, 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)*

K180819

Device Name

Menicon One Day Flat Pack (hioxifilcon A) Spherical and Multifocal Soft Contact Lenses

Indications for Use *(Describe)*

One Day Flat Pack (hioxifilcon A) Spherical Lens is indicated for daily wear single use only for the optical correction of refractive ametropia (myopia and hyperopia) in aphakic and non-aphakic persons with non-diseased eyes who may have 1.00 diopter (D) or less of astigmatism that does not interfere with visual acuity.

One Day Flat Pack (hioxifilcon A) Multifocal Lens is indicated for daily wear for the optical correction of refractive ametropia (myopia or hyperopia) and/or 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 1.00 D or less of astigmatism that does not interfere with visual acuity.

One Day Flat Pack (hioxifilcon A) Spherical and Multifocal Lenses are intended to be worn once and then discarded at the end of each wearing period on a daily basis. The lenses are not intended to be cleaned or disinfected and should be discarded after a single use.

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

One Day Flat Pack (hioxifilcon A) Multifocal Daily Disposable Soft Contact Lens

1. Applicant Information

Menicon Co., Ltd.
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JAPAN

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Date Prepared: May 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:	One Day Flat Pack (hioxifilcon A) Multifocal Daily Disposable Soft Contact Lens

3. Predicate Devices

Menicon claims substantial equivalence to K080632 Clear 1-Day (hioxifilcon A) Soft Contact Lens, K102895 One Day Flat Pack (hioxifilcon A) Daily Disposable Soft Contact Lens and K161739 Aquamax (etafilcon A) Soft Contact Lens.

4. Description of Device

The One Day Flat Pack (hioxifilcon A) Daily Disposable Soft Contact Lenses are daily wear disposable soft contact lenses available as spherical and multifocal lens designs. The hydrophilic nature of this material allows the lens to become soft and pliable when immersed in an aqueous solution.

The One Day Flat Pack Daily Disposable Contact Lens packaging system is designed to reduce lens handling by always presenting the lens anterior side up upon opening, which ensures correct lens orientation for proper insertion. The non-ionic lens material, (hioxifilcon A) is a random copolymer of 2- hydroxyethyl methacrylate (2-HEMA) and 2,3-Dihydroxypropyl Methacrylate (Glycerol Methacrylate, GMA) cross-linked with ethylene glycol dimethacrylate.

It consists of 43 % hioxifilcon A and 57 % water by weight when immersed in a buffered saline solution. The lens is available with a blue visibility-handling tint, color additive Reactive Blue # 19, 21 CFR part 73.3121.

5. Indications for Use

One Day Flat Pack (hioxifilcon A) Spherical Lens is indicated for daily wear single use only for the optical correction of refractive ametropia (myopia and hyperopia) in aphakic and non-aphakic persons with non-diseased eyes who may have 1.00 diopter (D) or less of astigmatism that does not interfere with visual acuity.

One Day Flat Pack (hioxifilcon A) Multifocal Lens is indicated for daily wear for the optical correction of refractive ametropia (myopia or hyperopia) and/or 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 1.00 D or less of astigmatism that does not interfere with visual acuity.

One Day Flat Pack (hioxifilcon A) Spherical and Multifocal Lenses are intended to be worn once and then discarded at the end of each wearing period on a daily basis. The lenses are not intended to be cleaned or disinfected and should be discarded after a single use.

6. Performance Data

Non-Clinical Data

Soft (hydrophilic) contact lenses composed of hioxifilcon A have been reviewed by the Food and Drug administration in eleven premarket 510(k) applications during the time period of 1998 to 2016. This application expands the indications for use for the One Day Flat Pack (hioxifilcon A) Daily Disposable Soft Contact lens to include a multifocal lens design. The change in lens design does not raise any new issues of safety and effectiveness of the hioxifilcon A material therefore no additional biocompatibility testing was required for this application.

Clinical Data

Clinical studies were unnecessary for this application. One Day Flat Pack (hioxifilcon A) Daily Disposable Soft Contact lenses are manufactured from the same material using similar manufacturing processes as the predicate devices.

Conclusion

Based upon the data presented, the One Day Flat Pack (hioxifilcon A) Multifocal Contact lens 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 devices is supported by the following Comparison of Characteristics in Table 1.

Table 1 Comparisons Of Characteristics

	One Day Flat Pack Multifocal	One Day Flat Pack Spherical	Pegavision Aquamax	Clear Lab 1 Day
510(k) Number	New	K102895	K161739	K080632
USAN	hioxifilcon A	hioxifilcon A	etafilcon A	hioxifilcon A
Product Code	LPL	LPL	LPL, MVN	LPL, MVN
Intended Use	Daily wear, single use, contact lens for the correction of visual acuity in aphakic and non-aphakic persons with non-diseased eyes with myopia or hyperopia	Daily wear, single use, contact lens for the correction of visual acuity in aphakic and non-aphakic persons with non-diseased eyes with myopia or hyperopia	Daily wear, frequent replacement, contact lens for the correction of visual acuity in aphakic and non-aphakic persons with non-diseased eyes with myopia or hyperopia	Daily wear, single use, contact lens for the correction of visual acuity in aphakic and non-aphakic persons with non-diseased eyes with myopia or hyperopia
Lens Designs	Spherical Aspherical Multifocal	Spherical	Spherical Aspherical Toric Multifocal	Spherical
Oxygen Permeability $\times 10^{-11}$ (cm^2/sec) (mL O_2/(mL x mm Hg))	25.38	25.38	19.73	25.38
Water Content*	57%	57%	58%	59.77 %
Refractive Index*	1.409	1.409	1.402	1.4011
Light Transmittance	>94 %	>94 %	>95 %	>95 %

* at 20 ° C

Based upon the comparison the One Day Flat Pack (hioxifilcon A) Multifocal Daily Disposable Soft Contact Lenses are substantially equivalent to the predicate devices.