June 17, 2020

Menicon Co., Ltd.
Li Haosheng, Ph.D.
International Regulatory Affairs
3-21-19, Aoi, Naka-ku
Nagoya, 460-0006 Japan

Re: K193399
Trade/Device Name: Miru 1day UpSide (midafilcon A)
Regulation Number: 21 CFR 886.5925
Regulation Name: Soft (Hydrophilic) Contact Lens
Regulatory Class: Class II
Product Code: LPL, MVN
Dated: May 15, 2020
Received: May 18, 2020

Dear Li Haosheng,

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see

https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

J. Angelo Green, Ph.D.
Assistant Director
DHT1A: Division of Ophthalmic Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT and Dental Devices
Office of Product Evaluation and Quality
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)*

K193399

Device Name

Miru 1day UpSide (midafilcon A)

Indications for Use *(Describe)*

The Miru 1day UpSide (midafilcon 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 people with disease free eyes who may have 1.50 diopter (D) or less of astigmatism.

The Miru 1day UpSide (midafilcon A) TORIC Lens is indicated for daily wear single use only for the optical correction of refractive ametropia (myopia or hyperopia with astigmatism) in aphakic and non-aphakic people with disease free eyes with 3.00 diopter (D) or less of refractive astigmatism.

The Miru 1day UpSide (midafilcon A) MULTIFOCAL Lens is indicated for daily wear single use only for the optical correction of refractive ametropia (myopia and hyperopia) and emmetropia with presbyopia in aphakic and non-aphakic people with disease free eyes who may require a reading addition of 3.00 diopter (D) or less and who may have 1.50 diopter (D) or less of astigmatism.

The Miru 1day UpSide (midafilcon A) should only be worn once and then discarded at the end of each wearing period on a daily basis. The patient should start the next wearing period with fresh lenses. The lenses should not 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

Miru 1day UpSide (midafilcon A)

1. Applicant Information

Menicon Co., Ltd.
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Nagoya, 460-0006 JAPAN

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Date Prepared: June 16, 2020

2. Device Information

Classification name: Soft (hydrophilic) Contact Lens
Device classification: Class II
Regulation number: 21 CFR 886.5925
Product code: LPL, MVN
Proprietary name: Miru 1day UpSide (midafilcon A)

3. Predicate Device

Menicon claims substantial equivalence to K160344 Visco Si-Hy (olifilcon B) Silicone Hydrogel Soft Contact Lens and K131378 CooperVision MyDay (stenfilcon A) Soft Contact Lens.

4. Description of Device

The Miru 1day UpSide (midafilcon A) is a hydrophilic contact lens which is available as a spherical, toric and multifocal lens. The lens is indicated for daily wear disposable single use.

The non-ionic lens material (midafilcon A) is a random co-polymer containing polydimethyl siloxane macromonomer. It consists of 46% midafilcon A and 54% water by weight when immersed in a buffered saline solution. The lens is available with a pale blue visibility handling tint.

The lens contains a benzotriazole UV absorbing monomer which is used to block UV radiation. The transmittance characteristics for the lens (-3.00D) are less than 5% of UVB radiation and less than 50% of UVA radiation.

5. Indications for Use

The Miru 1day UpSide (midafilcon 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 people with disease free eyes who may have 1.50 diopter (D) or less of astigmatism.

The Miru 1day UpSide (midafilcon A) TORIC Lens is indicated for daily wear single use only for the optical correction of refractive ametropia (myopia or hyperopia with astigmatism) in aphakic and non-aphakic people with disease free eyes with 3.00 diopter (D) or less of refractive astigmatism.

The Miru 1day UpSide (midafilcon A) MULTIFOCAL Lens is indicated for daily wear single use only for the optical correction of refractive ametropia (myopia and hyperopia) and emmetropia with presbyopia in aphakic and non-aphakic people with disease free eyes who may require a reading addition of 3.00 diopter (D) or less and who may have 1.50 diopter (D) or less of astigmatism.

The Miru 1day UpSide (midafilcon A) should only be worn once and then discarded at the end of each wearing period on a daily basis. The patient should start the next wearing period with fresh lenses. The lenses should not be cleaned or disinfected and should be discarded after a single use.

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 Miru 1day UpSide (midafilcon A). All tests were conducted in accordance with the GLP regulation (21 CFR Part 58) or according to valid scientific protocols.

The results of the non-clinical 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 randomized controlled clinical study was completed to evaluate the safety and efficacy of the Miru 1day UpSide (midafilcon A) contact lenses for daily wear, single use.

The study evaluated 148 male and female subjects who were randomized and dispensed lenses in a 1:1 ratio into the test and control groups. The efficacy outcome measures were lens visual acuity comparisons between the test and the control contact lenses. The safety outcome measures included adverse event rates, biomicroscopy and subjective acceptance.

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 Miru 1day UpSide (midafilcon A) 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 tables of Comparison of Characteristics.

Comparison of Characteristics (General Information)

	Miru 1day UpSide	**Visco Si-Hy**	**MyDay**
510(k)	K193399	K160344	K131378
USAN	midafilcon A	olifilcon B	stenfilcon A
Product Code	LPL, MVN	LPL, MVN	LPL, MVN
Modality	Daily wear, Single Use	Daily wear, Single Use	Daily wear, Single Use
FDA Lens Group	SiHy class 5	SiHy class 5	SiHy class 5
Device Classification	II	II	II
Manufacturing Method	Cast Molded	Cast Molded	Cast Molded
Sterilization	Moist Heat	Moist Heat	Moist Heat
Packaging	Blister Pack	Blister Pack	Blister Pack
Visibility Tint	Reactive Blue #246 Reactive Blue #247	Reactive Blue #19	Reactive Blue #246
Light Transmittance	> 92 %	94%	96%
Water Content	54% (USAN specification)	47%	54%
Refractive Index	1.403	1.410	1.401
Dk $\times 10^{-11}$ [$(cm^2/sec) \times (mL\ O_2)/(mL \times mm\ Hg)$]	64	120	80
Powers	- 20.00 to +20.00 D	- 20.00 to +20.00 D	- 20.00 to +20.00 D
Diameter	13.0 to 18.0 mm	13.0 to 15.0 mm	13.0 to 15.5 mm
Base Curve	8.0 to 9.0 mm	8.0 to 9.2 mm	8.4 and 8.7 mm
Optical Design	Spherical, Toric, Multifocal	Spherical, Toric, Multifocal	Aspherical, Toric, Multifocal, Multifocal Toric

Comparison of Characteristics (Indications for Use)

Miru 1day UpSide	Visco Si-Hy	MyDay
The Miru 1day UpSide (midafilcon 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 people with disease free eyes who may have 1.50 diopter (D) or less of astigmatism. The Miru 1day UpSide (midafilcon A) TORIC Lens is indicated for daily wear single use only for the optical correction of refractive ametropia (myopia or hyperopia with astigmatism) in aphakic and non-aphakic people with disease free eyes with 3.00 diopter (D) or less of refractive astigmatism. The Miru 1day UpSide (midafilcon A) MULTIFOCAL Lens is indicated for daily wear single use only for the optical correction of refractive ametropia (myopia and hyperopia) and emmetropia with presbyopia in aphakic and non-aphakic people with disease free eyes who may require a reading addition of 3.00 diopter (D) or less and who may have 1.50 diopter (D) or less of astigmatism. The Miru 1day UpSide (midafilcon A) should only be worn once and then discarded at the end of each wearing period on a daily basis. The patient should start the next wearing period with fresh lenses. The lenses should not be cleaned or disinfected and should be discarded after a single use.	The Si-Hy Spherical Silicone Hydrogel Soft Contact Lenses are indicated as daily wear single use soft contact lens for the correction of refractive ametropia (myopia and hyperopia) in phakic or aphakic persons with non-diseased eyes who exhibit refractive astigmatism of 1.00D or less where the astigmatism does not interfere with visual acuity. The Si-Hy Toric Silicone Hydrogel Soft Contact Lenses are indicated as daily wear for the correction of ametropia (myopia and hyperopia) with astigmatism in aphakic and non-aphakic persons with non-diseased eyes and whose powers are from -20.00 to +20.00 diopters and astigmatic corrections are from -0.75 to -2.25 diopters. The Si-Hy Multifocal Silicone Hydrogel Soft Contact lenses are indicated as daily wear for the correction of ametropia (myopia and hyperopia) and emmetropia with presbyopia in aphakic and non-aphakic persons with non-diseased eyes and whose powers are from -20.00 to +20.00 diopters with add powers from +0.75 to +2.75 diopters. The lenses may be worn by persons who exhibit astigmatism of 1.00 diopters or less where the astigmatism does not interfere with visual acuity. Eye care practitioners may prescribe the lens for daily wear (disposable use) single use. The lenses are to be discarded upon removal. Therefore, no cleaning or disinfecting is required.	MyDay ASPHERE Soft Contact lenses are indicated for the correctionof ametropia (myopia and hyperopia) in aphakic and non-aphakic persons with non-diseased eyes in powers from -20.00D to +20.00D diopters. The lenses may be worn by persons who exhibit astigmatism of -2.00 diopters or less that does not interfere with visual acuity. Toric: MyDay (stenfilcon A) Toric Soft Contact lenses are indicated for the correction of ametropia (myopia or hyperopia with astigmatism) in aphakic and non-aphakic persons with non-diseased eyes in powers from -20.00 to +20.00 diopters and astigmatic corrections from -0.25 to -10.00 diopters. Multifocal: MyDay (stenfilcon A) MULTIFOCAL Soft Contact lenses are indicated for the correction of refractive ametropia (myopia and hyperopia) and emmetropia with presbyopia in aphakic and non-aphakic persons with non-diseased eyes. The lenses may be worn by persons who exhibit astigmatism of -2.00 diopters or less that does not interfere with visual acuity. Multifocal Toric: MyDay (stenfilcon A) MULTIFOCAL TORIC Soft Contact lenses are indicated for the optical correction of distance and near vision in presbyopic phakic or aphakic persons with non-dieseased eyes who may have -10.00 diopters of astigmatism or less.