March 17, 2020

Johnson & Johnson Vision Care, Inc.
Mr. Scott Durland
Associate Director, Regulatory Affairs
7500 Centurion Parkway, Suite 100
Jacksonville, FL 32256

Re: K200243
Trade/Device Name: ACUVUE® (senofilcon A) Soft Contact Lens Multifocal, ACUVUE® (senofilcon A) Soft Contact Lens Multifocal Toric
Regulation Number: 21 CFR 886.5925
Regulation Name: Soft (Hydrophilic) Contact Lens
Regulatory Class: Class II
Product Code: LPL, MVN
Dated: January 29, 2020
Received: January 31, 2020

Dear Mr. Durland:

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)*
K200243

Device Name
ACUVUE® (senofilcon A) Soft Contact Lens MULTIFOCAL,
ACUVUE® (senofilcon A) Soft Contact Lens MULTIFOCAL TORIC

Indications for Use *(Describe)*
The ACUVUE® (senofilcon A) Soft Contact Lens MULTIFOCAL is indicated for daily wear for the optical correction of refractive ametropia (myopia and hyperopia) and/or presbyopia in phakic or aphakic persons with non-diseased eyes who may need up to 4.00 of ADD power and have 0.75D or less of astigmatism.

The ACUVUE® (senofilcon A) Soft Contact Lens MULTIFOCAL TORIC is indicated for daily wear for the optical correction of refractive ametropia (myopia, hyperopia, and/or astigmatism) and presbyopia in phakic or aphakic persons with non-diseased eyes who may need up to 4.00D of ADD power and may have 10.00D or less of astigmatism.

Eye Care Professionals may prescribe the lenses either for daily disposable wear or frequent/planned replacement wear with cleaning, disinfection and scheduled replacement. When prescribed for daily disposable wear, no cleaning or disinfection is required. Lenses should be discarded upon removal. When prescribed for frequent/planned replacement wear, the lenses may be disinfected using a chemical disinfection system only and should be discarded after the recommended wearing period as prescribed by the Eye Care Professional.

When the lenses are worn in a frequent/planned replacement modality, they are intended to be worn for up to 2 weeks (14 days).

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

Submitter Information

Company:	Johnson & Johnson Vision Care, Inc. 7500 Centurion Parkway, Suite 100 Jacksonville, FL 32256
Contact Person:	Scott Durland
Email:	sdurland@its.jnj.com
Telephone:	904-443-3458
FAX:	904-443-1424
Date:	January 31, 2020

Identification of the Device

Common Name:	Soft Contact Lens
Device/Trade Name:	ACUVUE® (senofilcon A) Soft Contact Lens Multifocal
	ACUVUE® (senofilcon A) Soft Contact Lens Multifocal Toric
Classification Name:	Soft (Hydrophilic) Contact Lens, Daily Wear
Device Classification:	Class II, 21 CFR 886.5925 (b) (1)
Product Code:	LPL, MVN

Predicate Device:

- VISTAKON® (senofilcon A) Contact Lens, cleared via K042275

Reference Device: Optical Design

- ACUVUE® (etafilcon A) Soft Contact Lens for Presbyopia, Clear and Tinted (Visibility and/or Cosmetically) with UV Blocker for Daily Wear, cleared via K141670

Description of Device

The subject device is a soft (hydrophilic) contact lens available in a multifocal and/or multifocal toric design. The composition of the lens is 62% senofilcon A and 38% water by weight when hydrated and stored in the buffered saline solution with methyl ether cellulose. The lens is supplied sterile (steam) in a foil sealed plastic package. The lenses are hemispherical or hemitoric shells.

The subject device is made of a silicone hydrogel material containing an internal wetting agent. The lens is tinted blue using Reactive Blue Dye #4 to make the lens more visible for handling. A benzotriazole UV absorbing monomer is used to block UV radiation. The transmittance characteristics for these lenses are less than 1.0% in the UVB range of 280 nm to 315 nm and less than 10.0% in the UVA range of 315 nm to 380 nm for the entire power range.

Table 1 details properties and parameters of the subject device.

Table 1: Physicochemical Properties and Parameters

Property / Parameter	Subject Device
Water Content	38%
Refractive Index	1.42
Oxygen Permeability (Fatt method, edge corrected)	103 x 10^{-11} (cm^2/sec)(mL O_2/mL * mm Hg)
Oxygen Permeability (Fatt method, non-edge corrected)	122 x 10^{-11} (cm^2/sec)(mL O_2/mL * mm Hg)
Light Transmittance: Visible	89% to 99%
Light Transmittance: UVA (315 nm to 380 nm)	< 10.0%
Light Transmittance: UVB (280 nm to 315 nm)	< 1.0%
DCA Advancing Contact Angle (degree)	38 – 74
Diameter	12.0 mm to 15.0 mm
Center Thickness, varies with power	0.060 – 1.000 mm -3.00D: 0.070 mm +3.00D: 0.147 mm
Base Curve	7.85 mm to 10.00 mm
Sphere Powers	-20.00D to +20.00D
ADD Powers	Up to +4.00D
Axis	2.5° to 180°
Cylinder	-0.25D to -10.00D

Indications for Use

The intended use of ACUVUE® (senofilcon A) Soft Contact Lens MULTIFOCAL is for vision correction in a presbyopic population. The specific indications for use are provided below followed by a comparison to the predicate device in **Table 2**.

The ACUVUE® OASYS (senofilcon A) Soft Contact Lens MULTIFOCAL is indicated for daily wear for the optical correction of refractive ametropia (myopia and hyperopia) and/or presbyopia in phakic or aphakic persons with non-diseased eyes who may need up to 4.00 of ADD power and have 0.75D or less of astigmatism.

The ACUVUE® OASYS (senofilcon A) Soft Contact Lens MULTIFOCAL TORIC is indicated for daily wear for the optical correction of refractive ametropia (myopia, hyperopia, and/or astigmatism) and presbyopia in phakic or aphakic persons with non-diseased eyes who may need up to 4.00D of ADD power and may have 10.00D or less of astigmatism.

Eye Care Professionals may prescribe the lenses either for daily disposable wear or frequent/planned replacement wear with cleaning, disinfection and scheduled replacement. When prescribed for daily disposable wear, no cleaning or disinfection is required. Lenses should be

discarded upon removal. When prescribed for frequent/planned replacement wear, the lenses may be disinfected using a chemical disinfection system only and should be discarded after the recommended wearing period as prescribed by the Eye Care Professional.

When the lenses are worn in a frequent/planned replacement modality, they are intended to be worn for up to 2 weeks (14 days).

Table 2: Indication Comparison

Indication	Predicate Device (K042275)	Subject Device
Multifocal	For daily wear for the correction of distance and near vision in presbyopic, phakic or aphakic persons with non-diseased eyes who may have 0.75D of astigmatism or less.	For daily wear for the optical correction of refractive ametropia (myopia and hyperopia) and/or presbyopia in phakic or aphakic persons with non-diseased eyes who may need up to 4.00D of ADD power and have 0.75D of astigmatism or less.
Multifocal Toric	For daily wear for the correction of distance and near vision in presbyopic phakic or aphakic persons with non-diseased who may have 10.00D of astigmatism or less.	For daily wear for the optical correction of refractive ametropia (myopia, hyperopia, and/or astigmatism) and presbyopia in phakic or aphakic persons with non-diseased eyes who may need up to 4.00D of ADD power and have 10.00D of astigmatism or less.
Wear/ Replacement Schedule	Eye Care Practitioners may prescribe the lenses either for single-use disposable wear or frequent/planned replacement wear with cleaning, disinfection and scheduled replacement. When prescribed for frequent/planned replacement wear, the lenses may be disinfected using a chemical disinfection system only.	Eye Care Professionals may prescribe the lenses either for daily disposable wear or frequent/planned replacement wear with cleaning, disinfection and scheduled replacement. When prescribed for daily disposable wear, no cleaning or disinfection is required. Lenses should be discarded upon removal. When prescribed for frequent/planned replacement wear, the lenses may be disinfected using a chemical disinfection system only and should be discarded after the recommended wearing period as prescribed by the Eye Care Professional. When the lenses are worn in a frequent/planned replacement modality, they are intended to be worn for up to 2 weeks (14 days).

Technological Characteristics

The technological characteristics of the subject device are compared to the characteristics of the predicate and reference devices in **Table 3.**

Table 3: Material & Physicochemical Comparison

Property	Predicate Device (K042275)	Reference Device (K141670)	Subject Device
Optical Design Type	Alternating zone	Progressive asphere	Progressive asphere
Material	senofilcon A	etafilcon A	senofilcon A
Material Classification Group[a]	Group VC (Enhanced Oxygen Permeable: low water sub group)	Group IV (High water, ionic polymer)	Group VC (Enhanced Oxygen Permeable: low water sub group)
UV Blocker	Yes	Yes	Yes
Water Content, %	38	58	38
Refractive Index	1.42	1.40	1.42
Oxygen Permeability (Dk)[b]	103[c] 122[d]	21.4[c] 28.0[d]	103[c] 122[d]
Specific Gravity (calculated)	0.98-1.12	0.98-1.13	0.98-1.12

[a] As referenced in ANSI Z80.20-2016, section 4.2, Material Classification
[b] Dk units = x 10^{-11} (cm^2/sec)(mL O_2/mL * mm Hg)
[c] 35°C Fatt method, edge corrected
[d] 35°C Fatt method, non-edge corrected

Non-clinical Performance Data

The device uses the same manufacturing process and is made from the same material as the predicate device, VISTAKON® (senofilcon A). Therefore, all nonclinical testing supporting the predicate device in K042275 is also representative of the subject device.

Additionally, in accordance with FDA Premarket Notification (510(k)) Guidance Document *for Daily Wear Contact Lenses*, May 12, 1994, finished product testing for verification of the modified design was conducted to demonstrate that lenses meet specification tolerances.

Clinical Performance Data

The proposed alternative multifocal and multifocal toric designs have the same indications, use the same material, senofilcon A, and utilize the same manufacturing and sterilization processes as the predicate device in K042275. Additionally, the optical design type is the same as the reference device in K141670. Demonstration of the physical and chemical equivalency of the subject device to the predicate device and design equivalence to the reference device supports the safety and effectiveness of the subject device for an alternate multifocal and multifocal toric lens design configuration. Therefore, in accordance with FDA *Premarket Notification (510(k)) Guidance Document for Daily Wear Contact Lenses,* May 12, 1994, clinical performance data to demonstrate substantial equivalence are not required.

Conclusions Drawn from the Non-clinical and Clinical Tests

Substantial Equivalence: Information presented in this Premarket Notification establishes that the ACUVUE® (senofilcon A) Soft Contact Lens MULTIFOCAL is as safe and effective as the predicate device when used in accordance with the labeled directions for use.

Risk and Benefits: The risks of the subject device are the same as those normally attributed to the wearing of soft (hydrophilic) contact lenses on a daily wear basis. The benefits to the patient are the same as those for other soft (hydrophilic) contact lenses.

Other Information

Not applicable.