April 10, 2018

Johnson & Johnson Vision Care, Inc.
Victoria Brennand
Manager, Regulatory Affairs
7500 Centurion Parkway, Suite 100
Jacksonville, FL 32256

Re: K180299
Trade/Device Name: ACUVUE OASYS (senofilcon A) with Photochromic Additive
Regulation Number: 21 CFR 886.5925
Regulation Name: Soft (Hydrophilic) Contact Lens
Regulatory Class: Class II
Product Code: LPL, MVN
Dated: January 31, 2018
Received: February 2, 2018

Dear Victoria Brennand:

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,

Denise L. Hampton -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)*

K180299

Device Name
ACUVUE (senofilcon A) Soft (hydrophilic) Contact Lens with photochromic additive

Indications for Use *(Describe)*

The ACUVUE (senofilcon A) Soft (hydrophilic) Contact Lens with photochromic additive (spherical) is indicated for daily wear for the optical correction of refractive ametropia (myopia and hyperopia) in phakic or aphakic persons with non-diseased eyes who may have 1.00D or less of astigmatism.

The ACUVUE (senofilcon A) Soft (hydrophilic) Contact Lens with photochromic additive TORIC is indicated for daily wear for the optical correction of refractive ametropia (myopia and hyperopia) in phakic or aphakic persons with non-diseased eyes who may have 10.00D or less of astigmatism.

The ACUVUE (senofilcon A) Soft (hydrophilic) Contact Lens with photochromic additive 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 have 0.75D or less of astigmatism.

The ACUVUE (senofilcon A) Soft (hydrophilic) Contact Lens with photochromic additive 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.

These lenses are also indicated for the attenuation of bright light as they contain a photochromic additive which dynamically absorbs visible light.

These lenses contain a UV Blocker to help protect against transmission of harmful UV radiation to the cornea and into the eye.

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.

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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:	Victoria Brennand
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Telephone:	(904) 443-3160
FAX:	(904) 443-1424
Date:	January 31, 2018

Identification of the Device

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

Predicate Device

- ACUVUE OASYS® (senofilcon A) Brand Contact Lens cleared via K042275

Description of Device

The subject device is a soft (hydrophilic) contact lens available in a spherical, toric, 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. To date a 2-year shelf-life has been established.

The subject device is made of a silicone hydrogel material containing an internal wetting agent and UV absorbing monomers. A combination of a benzotriazole UV absorbing monomer and a naphthopyran monomer (photochromic additive) is used to block UV radiation and dynamically absorbs visible light. 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 316 nm to 380 nm for the entire power range.

Additionally, the photochromic additive absorbs visible light in the range from 380 nm to 780 nm to a minimum 84% transmittance in the inactivated (closed) state. The activated (open) state dynamically absorbs visible light dependent on the lens thickness and the level of UV and high energy visible (HEV) radiation to a minimum of 23% transmittance.

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)	103×10^{-11} $(cm^2/sec)(mL\ O_2/mL * mm\ Hg)$
Oxygen Permeability (Fatt method, non-edge corrected)	122×10^{-11} $(cm^2/sec)(mL\ O_2/mL * mm\ Hg)$
Light Transmittance: Visible – closed form	84% to 94%
Light Transmittance: Visible – open form calculated from Delta Optical Density	Minimum 23%[a]
Light Transmittance: UVA (316 nm to 380 nm)	< 10.0%
Light Transmittance: UVB (280 nm to 315 nm)	< 1.0%
Diameter	12.0 mm to 15.0 mm
Center Thickness, varies with power	0.060 – 1.000 mm -3.00D: 0.085 mm +3.00D: 0.168 mm
Base Curve	7.85 mm to 10.00 mm
Sphere Powers	-20.00D to +20.00D

Table 1: Physicochemical Properties and Parameters (Continued)

Property / Parameter	Subject Device
ADD Powers	+0.25D to +4.00D
Axis	2.5° to 180°
Cylinder	-0.25D to -10.00D

[a] Luminous transmission from nominal delta optical density range 0.31 to 0.53

Indications for Use

The ACUVUE® (senofilcon A) Soft (hydrophilic) Contact Lens with photochromic additive (spherical) is indicated for daily wear for the optical correction of refractive ametropia (myopia and hyperopia) in phakic or aphakic persons with non-diseased eyes who may have 1.00D or less of astigmatism.

The ACUVUE® (senofilcon A) Soft (hydrophilic) Contact Lens with photochromic additive TORIC is indicated for daily wear for the optical correction of refractive ametropia (myopia and hyperopia) in phakic or aphakic persons with non-diseased eyes who may have 10.00D or less of astigmatism.

The ACUVUE® (senofilcon A) Soft (hydrophilic) Contact Lens with photochromic additive 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 have 0.75D or less of astigmatism.

The ACUVUE® (senofilcon A) Soft (hydrophilic) Contact Lens with photochromic additive 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.

These lenses are also indicated for the attenuation of bright light as they contain a photochromic additive which dynamically absorbs visible light.

These lenses contain a UV Blocker to help protect against transmission of harmful UV radiation to the cornea and into the eye.

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 device in **Table 2** and **Table 3.**

Table 2: Material & Physicochemical Comparison

Property	Predicate Device	Subject Device
Material	senofilcon A	senofilcon A
ISO Classification Group[a]	Group 5C (Silicone hydrogel: low water sub group)	Group 5C (Silicone hydrogel: low water sub group)
UV Blocker	Yes	Yes
Photochromic Additive	No	Yes
Water Content, %	38	38
Refractive Index	1.42	1.42
Oxygen Permeability (Dk)[b]	103[c] 122[d]	103[c] 122[d]
Specific Gravity (calculated)	0.98-1.12	0.98-1.12

[a] As referenced in ISO 18369-1:2017
[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

Table 3a: Indication Comparison

Indication	Predicate Device	Subject Device
Spherical	For the optical correction of refractive ametropia (myopia and hyperopia) in phakic or aphakic persons with non-diseased eyes who have 1.00D or less of astigmatism.	Same as predicate
Toric	For the optical correction of visual acuity in phakic or aphakic persons with non-diseased eyes that are hyperopic or myopic and may have 10.00D or less of astigmatism.	Same as predicate
Multifocal	For the optical correction of distance and near vision in presbyopic, phakic or aphakic persons with non-diseased eyes who may have 0.75D or less of astigmatism.	Same as predicate
Multifocal-Toric	For the optical correction of distance and near vision in presbyopic phakic or aphakic persons with non-diseased eyes who may have 10.00D of astigmatism or less.	Same as predicate
Attenuation of bright light	N/A	These lenses are also indicated for the attenuation of bright light as they contain a photochromic additive which dynamically absorbs visible light.
UV Statement	Contain a UV Blocker to help protect against transmission of harmful UV radiation to the cornea and into the eye.	Same as predicate

Table 3b: Wear/ Replacement Schedule Comparison

Wear/ Replacement Schedule	Predicate Device	Subject Device
	Eye Care Professionals 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 cleaned and disinfected using a chemical disinfection system only.	Same as predicate

Non-clinical Performance Data

A series of *in-vitro* and *in-vivo* tests were performed to assess the properties and safety and effectiveness of the contact lens following the 1994 FDA Guidance Document for Daily Wear Contact Lenses. All biocompatibility tests were conducted in accordance with the GLP regulation (21 CFR Part 58). All other testing was conducted according to valid scientific protocols.

Non-Clinical testing performed includes:

- Physicochemical Properties
  - Refractive Index
  - Oxygen Permeability
  - Specific Gravity
  - Modulus
  - Tensile Strength
  - Elongation
  - Dynamic Contact Angle
  - Leachables
  - Light Transmittance
  - Photochromic Performance
- Biocompatibility
  - Bacterial Reverse Mutation Study (according to ISO 10993-3:2003)
  - In Vitro Chromosomal Aberration Study in Chinese Hamster Ovary Cell (according to ISO 10993-3:2003)
  - Cytotoxicity Study Using the ISO Direct Contact Method (according to ISO 10993-5:2009). Conducted before and after photochromic transitioning of the lens
  - Cytotoxicity Study Using the Colony Assay (Extraction Method) (according to ISO 10993-5:2009). Conducted before and after photochromic transitioning of the lens
  - 22-Day Rabbit Contact Lens Study (according to ISO 9394:2012)
  - ISO Ocular Irritation Study in Rabbits (according to ISO 10993-10:2010)
  - ISO Acute Systemic Toxicity Study in Mice (according to ISO 10993-11:2006)
  - Guinea Pig Maximization Sensitization Study (according to ISO 10993-10:2010)
- Solution Compatibility (according to ISO 11981:2009) and Preservative Uptake and Release (according to ISO 11986:2010)

- Clear Care® Plus Cleaning and Disinfecting Solution
- RevitaLens® Blink® Multi-Purpose Disinfecting Solution
- OPTI-FREE® PureMoist® Multi-Purpose Disinfecting Solution
- Biotrue® Multi-Purpose Solution

The results of the non-clinical testing on the subject device demonstrate that:

- the lens material and extracts are non-toxic and non-irritating, and
- lens physical and material properties are consistent with currently marketed lenses with the exception of photochromic performance (Delta OD)

Clinical Performance Data

A clinical study was conducted in Australia to evaluate the effect of the subject device on vision and driving performance in both daytime and nighttime lighting under real world driving conditions. This was achieved through field-based driving studies on a closed-road driving circuit at night and during the day. Quantitative methods were used to assess vision and driving performance under a range of challenging conditions. Appropriate masking, order of testing, randomization and control conditions were used.

The study evaluated 24 subjects in a bilateral, non-dispensing, randomized, partially masked (subject), crossover study. Primary endpoint was overall driving performance score. Secondary endpoint(s) included low luminance high contrast distance visual acuity; distance visual acuity (~1 lux); low luminance (~1 lux) contrast threshold; road sign recognition (percentage); percentage of hazards avoidance and pedestrian recognition distance.

The results of the clinical testing demonstrate there was no evidence of driving performance or visual acuity concerns while wearing the subject device during daytime and nighttime driving.

Conclusions Drawn from the Non-clinical and Clinical Tests

Substantial Equivalence: Information presented in this Premarket Notification establishes that the subject device is as safe and effective as the predicate device when used for the proposed indication, in accordance with the labeled directions for use. All potential risks associated with the proposed modification, the addition of a photochromic additive, intended for the attenuation of bright light, have been thoroughly addressed. No new questions of safety and efficacy compared to the predicate device have been identified.

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 with the additional benefit of the attenuation of bright light.

Other Information

Not applicable.