November 29, 2021

Johnson & Johnson Vision Care, Inc.
Jamie Frenz-Ross
Manager, Regulatory Affairs
7500 Centurion Parkway, Suite 100
Jacksonville, Florida 32256

Re: K210930
Trade/Device Name: ACUVUE® OASYS MAX 1-DAY Contact Lenses (senofilcon A)
Regulation Number: 21 CFR 886.5925
Regulation Name: Soft (Hydrophilic) Contact Lens
Regulatory Class: Class II
Product Code: LPL, MVN
Dated: October 28, 2021
Received: October 29, 2021

Dear Jamie Frenz-Ross:

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: 06/30/2023
*See PRA Statement below.*

510(k) Number *(if known)*
K210930

Device Name
ACUVUE® OASYS MAX 1-DAY Contact Lenses (senofilcon A)

Indications for Use *(Describe)*
ACUVUE® OASYS MAX 1-DAY Contact Lenses (senofilcon A) are indicated for daily disposable wear for the correction of vision in people with non-diseased eyes who are nearsighted (myopic) or farsighted (hyperopic) and may have 1.00D or less of astigmatism that does not interfere with visual acuity.

ACUVUE® OASYS MAX 1-DAY Contact Lenses for ASTIGMATISM (senofilcon A) are indicated for daily disposable wear for the correction of vision in people with non-diseased eyes who may be nearsighted (myopic) or farsighted (hyperopic) and have 10.00D or less of astigmatism.

ACUVUE® OASYS MAX 1-DAY MULTIFOCAL Contact Lenses (senofilcon A) are indicated for daily disposable wear for the correction of vision in people with non-diseased eyes who are presbyopic and may be nearsighted (myopic) or farsighted (hyperopic) and may have 0.75D or less of astigmatism that does not interfere with visual acuity.

ACUVUE® OASYS MAX 1-DAY MULTIFOCAL Contact Lenses for ASTIGMATISM (senofilcon A) are indicated for daily disposable wear for the correction of vision in people with non-diseased eyes who are presbyopic and may be nearsighted (myopic) or farsighted (hyperopic) and have 10.00D or less of astigmatism.

The lenses are to be prescribed for daily disposable wear. Therefore, no cleaning or disinfection is required. Lenses should be discarded upon removal.

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

## Submitter Information

| | |
|---|---|
| Company: | Johnson & Johnson Vision Care, Inc.<br>7500 Centurion Parkway, Suite 100<br>Jacksonville, FL 32256 |
| Contact Person: | Jamie Frenz-Ross |
| Email: | jfrenzro@its.jnj.com |
| Telephone: | 561-373-7697 |
| Date: | November 19, 2021 |

## Identification of the Device

| | |
|---|---|
| Common Name: | Soft Contact Lens |
| Device/Trade Name: | ACUVUE® OASYS MAX 1-DAY Contact Lenses (senofilcon A) |
| 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) Soft Contact Lens, cleared via K042275

## Reference Device: Multifocal and Multifocal Toric Optical Designs

- 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 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. The lens is tinted using Reactive Blue 247. A benzotriazole UV absorbing monomer is used to block UV radiation in combination with a novel fused tricyclic chromophore that also blocks UV radiation and reduces transmittance in the range from 380 nm to 450 nm.

**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) | $103 \times 10^{-11}$ ($cm^2$/sec)(mL $O_2$/mL * mm Hg) |
| Light Transmittance: Visible (380 nm to 780 nm), varies with power | ≥ 78% |
| Light Transmittance: (451 nm to 780 nm) | ≥ 90% |
| Light Transmittance: (380 nm to 450 nm) | ≤ 45% |
| Light Transmittance: UVA (315 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<br>-3.00D: 0.085 mm<br>+3.00D: 0.173 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

ACUVUE® OASYS MAX 1-DAY Contact Lenses (senofilcon A) are indicated for daily disposable wear for the correction of vision in people with non-diseased eyes who are nearsighted (myopic) or farsighted (hyperopic) and may have 1.00D or less of astigmatism that does not interfere with visual acuity.

ACUVUE® OASYS MAX 1-DAY Contact Lenses for ASTIGMATISM (senofilcon A) are indicated for daily disposable wear for the correction of vision in people with non-diseased eyes who may be nearsighted (myopic) or farsighted (hyperopic) and have 10.00D or less of astigmatism.

ACUVUE® OASYS MAX 1-DAY MULTIFOCAL Contact Lenses (senofilcon A) are indicated for daily disposable wear for the correction of vision in people with non-diseased eyes who are presbyopic and may be nearsighted (myopic) or farsighted (hyperopic) and may have 0.75D or less of astigmatism that does not interfere with visual acuity.

ACUVUE® OASYS MAX 1-DAY MULTIFOCAL Contact Lenses for ASTIGMATISM (senofilcon A) are indicated for daily disposable wear for the correction of vision in people with non-diseased eyes who are presbyopic and may be nearsighted (myopic) or farsighted (hyperopic) and have 10.00D or less of astigmatism.

The lenses are to be prescribed for daily disposable wear. Therefore, no cleaning or disinfection is required. Lenses should be discarded upon removal.

## Technological Characteristics

The technological characteristics of the subject device are compared to the characteristics of the predicate and reference devices in **Table 2** and **Table 3**.

The single vision and toric optical designs for the subject device are the same as the predicate optical lens designs. The multifocal and multifocal toric optical designs for the subject device are the same as the reference device optical lens designs.

**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 subgroup) | Group 5C (Silicone hydrogel: low water subgroup) |
| UV Blocker | Yes | Yes |
| Water Content, % | 38 | 38 |
| Refractive Index | 1.42 | 1.42 |
| Oxygen Permeability (Dk)[b] | 103 | 103 |
| 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), 35°C Fatt method, edge corrected

**Table 3: Indication Comparison**

| Indication | Predicate Device | Subject Device |
|---|---|---|
| Spherical | For daily wear for the correction of refractive ametropia (myopia and hyperopia) in phakic or aphakic persons with non-diseased eyes who have 1.00D or less of astigmatism. | For daily disposable wear for the correction of vision in people with non-diseased eyes who are nearsighted (myopic) or farsighted (hyperopic) and may have 1.00D or less of astigmatism that does not interfere with visual acuity. |
| Toric | For daily wear for the 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. | For daily disposable wear for the correction of vision in people with non-diseased eyes who may be nearsighted (myopic) or farsighted (hyperopic) and have 10.00D or less of astigmatism. |
| 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 or less of astigmatism. | For daily disposable wear for the correction of vision in people with non-diseased eyes who are presbyopic and may be nearsighted (myopic) or farsighted (hyperopic) and may have 0.75D or less of astigmatism that does not interfere with visual acuity. |
| Multifocal Toric | For daily wear for the 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. | For daily disposable wear for the correction of vision in people with non-diseased eyes who are presbyopic and may be nearsighted (myopic) or farsighted (hyperopic) and have 10.00D or less of astigmatism. |

**Table 4: 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. | The lenses are to be prescribed for daily disposable wear. Therefore, no cleaning or disinfection is required. Lenses should be discarded upon removal. |

## 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
- Biocompatibility
  - Bacterial Reverse Mutation Study (according to ISO 10993-3:2014)
  - Cytotoxicity Study Using the ISO Direct Contact Method (according to ISO 10993-5:2009).
  - 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 10993-11:2017)
  - Guinea Pig Maximization Sensitization Study (according to ISO 10993-10:2010)

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

**Note**: The packing solution and packaging system are the same as referenced in K042275.

## Clinical Performance Data

The subject device uses the same lens material, senofilcon A, has the same indications, has the same sphere and toric lens designs and utilizes the same manufacturing and sterilization processes as the predicate device in K042275. Additionally, the multifocal and multifocal toric optical design types are the same as the reference device in K141670.

Demonstration of the physical, chemical and sphere/toric optical design equivalency of the subject device to the predicate device and multifocal design equivalency to the reference device supports the safety and effectiveness of the subject device. 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 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 in accordance with the labeled directions for use. All potential risks associated with the proposed modification, 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.

## Other Information

Not applicable.