March 28, 2016

Johnson & Johnson Vision Care, Inc.
Ramona Haile, Pharm.D.
Senior Manager, Regulatory Affairs
7500 Centurion Parkway, Suite 100
Jacksonville, FL 32256

Re: K160212
Trade/Device Name: ACUVUE® VITA™ (senofilcon C) Brand (Soft) Contact Lens
ACUVUE® VITA™ (senofilcon C) Brand (Soft) Contact Lens for ASTIGMATISM
ACUVUE® VITA™ (senofilcon C) Brand (Soft) MULTIFOCAL Contact Lens
ACUVUE® VITA™ (senofilcon C) Brand (Soft) MULTIFOCAL Contact Lens for ASTIGMATISM

Regulation Number: 21 CFR 886.5925
Regulation Name: Soft (Hydrophilic) Contact Lens
Regulatory Class: Class II
Product Code: LPL, MVN
Dated: January 27, 2016
Received: January 29, 2016

Dear Dr. Haile:

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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

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
Indications for Use

Device Name
ACUVUE® (senofilcon C) Soft Contact Lens

Indications for Use (Describe)
The ACUVUE® (senofilcon C) Soft (hydrophilic) Contact Lens (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 C) Soft (hydrophilic) Contact Lens 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 C) Soft (hydrophilic) 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 4.00D of ADD power and may have 0.75D of astigmatism or less.

The ACUVUE® (senofilcon C) Soft (hydrophilic) 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 of astigmatism or less.

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 (see REPLACEMENT SCHEDULE). When prescribed for daily disposable wear, lenses should be discarded upon removal. When prescribed for frequent/planned replacement wear, the lenses may be disinfected using a chemical disinfection system only. The contact lens is to be discarded after the recommended wearing period as prescribed by the Eye Care Professional.

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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5. 510(K) SUMMARY

Submitter Information
Company: Johnson & Johnson Vision Care, Inc.
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Jacksonville, FL 32256
Contact Person: Ramona Haile
Email: rhaile@its.jnj.com
Telephone: 904-443-1191
FAX: 904-443-1424
Date: March 18, 2016

Identification of the Device
Common Name: Soft Contact Lens
Device/Trade Name: ACUVUE® VITA™ (senofilcon C) Brand (Soft) Contact Lens
ACUVUE® VITA™ (senofilcon C) Brand (Soft) Contact Lens for ASTIGMATISM
ACUVUE® VITA™ (senofilcon C) Brand (Soft) MULTIFOCAL Contact Lens
ACUVUE® VITA™ (senofilcon C) Brand (Soft) MULTIFOCAL Contact Lens for ASTIGMATISM

Classification Name: Soft (Hydrophilic) Contact Lens, Daily Wear
Device Classification: Class II, 21 CFR 886.5925 (b) (1)
Product Code: LPL, MVN

Predicate Device
- CooperVision Biofinity® (comfilcon A) Soft Contact Lens cleared via K052560,
  hereafter also referred to as CooperVision (comfilcon A) or Biofinity®

1 Biofinity® is a registered trademark of CooperVision, Inc.
Description of Device

The ACUVUE® (senofilcon C) Soft Contact Lens is a soft (hydrophilic) contact lens available in a spherical, toric, multifocal and/or multifocal-toric design. The composition of the lens is 59% senofilcon C and 41% water by weight when hydrated and stored in 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 4-year shelf-life has been established.

The ACUVUE® (senofilcon C) Soft Contact Lens 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 are less than 1% in the UVB range of 280 nm to 315 nm and less than 10% in the UVA range of 316 nm to 380 nm for the entire power range.

Table 1 contains property and parameter ranges for the subject device.

Table 1: Physicochemical Properties and Parameters

<table>
<thead>
<tr>
<th>Property / Parameter</th>
<th>Subject Device</th>
</tr>
</thead>
<tbody>
<tr>
<td>Water Content</td>
<td>41%</td>
</tr>
<tr>
<td>Refractive Index</td>
<td>1.42</td>
</tr>
<tr>
<td>Oxygen Permeability (Fatt method, edge corrected)</td>
<td>$103 \times 10^{-11} (\text{cm}^2/\text{sec})(\text{mL O}_2/\text{mL} \times \text{mm Hg})$</td>
</tr>
<tr>
<td>Oxygen Permeability (Fatt method, non-edge corrected)</td>
<td>$122 \times 10^{-11} (\text{cm}^2/\text{sec})(\text{mL O}_2/\text{mL} \times \text{mm Hg})$</td>
</tr>
<tr>
<td>Light Transmission - Visible</td>
<td>89 to 99%</td>
</tr>
<tr>
<td>Light Transmission - UVA (316 nm to 380 nm)</td>
<td>&lt; 10.0%</td>
</tr>
<tr>
<td>Light Transmission - UVB (280 nm to 315 nm)</td>
<td>&lt; 1.0%</td>
</tr>
<tr>
<td>Diameter</td>
<td>12.0 mm to 15.0 mm</td>
</tr>
<tr>
<td>Center Thickness, varies with power</td>
<td>0.060 – 1.000 mm</td>
</tr>
<tr>
<td></td>
<td>-3.00D: 0.070 mm</td>
</tr>
<tr>
<td></td>
<td>+3.00D: 0.168 mm</td>
</tr>
<tr>
<td>Base curve</td>
<td>7.85 mm to 10.00 mm</td>
</tr>
<tr>
<td>Sphere Powers</td>
<td>-20.00D to +20.00D</td>
</tr>
<tr>
<td>ADD powers</td>
<td>+0.25D to +4.00D</td>
</tr>
<tr>
<td>Axis</td>
<td>2.5° to 180°</td>
</tr>
<tr>
<td>Cylinder</td>
<td>-0.25D to -10.00D</td>
</tr>
</tbody>
</table>

Note: UVA = ultraviolet A, UVB = ultraviolet B
Indications for Use

ACUVUE® (senofilcon C) Soft (hydrophilic) Contact Lens (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.

ACUVUE® (senofilcon C) Soft (hydrophilic) Contact Lens – 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.

ACUVUE® (senofilcon C) Soft (hydrophilic) 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 4.00D of ADD power and may have 0.75D or less of astigmatism.

ACUVUE® (senofilcon C) Soft (hydrophilic) 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.

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 (see REPLACEMENT SCHEDULE). When prescribed for daily disposable wear, lenses should be discarded upon removal. When prescribed for frequent/planned replacement wear, the lenses may be disinfected using a chemical disinfection system only. The contact lens is to be discarded after the recommended wearing period as prescribed by the Eye Care Professional.

Technological Characteristics

The technological characteristics of the ACUVUE® (senofilcon C) Soft Contact Lens are compared to the characteristics of the predicate device, CooperVision (comfilcon A) in Table 2 and Table 3.
<table>
<thead>
<tr>
<th>Property</th>
<th>Predicate Device&lt;sup&gt;a&lt;/sup&gt; (K052560)</th>
<th>Subject Device</th>
</tr>
</thead>
<tbody>
<tr>
<td>Material</td>
<td>comfilcon A</td>
<td>senofilcon C</td>
</tr>
<tr>
<td>Lens Material Group</td>
<td>Group V (Silicone Hydrogel)</td>
<td>Group V (Silicone Hydrogel)</td>
</tr>
<tr>
<td>UV Blocker</td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td>Water Content, %</td>
<td>48</td>
<td>41</td>
</tr>
<tr>
<td>Refractive Index</td>
<td>1.40</td>
<td>1.42</td>
</tr>
<tr>
<td>Oxygen Permeability (Dk)&lt;sup&gt;b&lt;/sup&gt;</td>
<td>128&lt;sup&gt;c&lt;/sup&gt;</td>
<td>103&lt;sup&gt;d&lt;/sup&gt;</td>
</tr>
<tr>
<td>Specific Gravity (calculated)</td>
<td>1.04</td>
<td>0.98-1.12</td>
</tr>
</tbody>
</table>

<sup>a</sup> Based on available public information

<sup>b</sup> Dk units = x 10\(^{-11}\) (cm\(^2\)/sec)(mL O\(_2\)/mL * mm Hg)

<sup>c</sup> 34°C Coulometric method

<sup>d</sup> 35°C Fatt method, edge corrected

<sup>e</sup> 35°C Fatt method, non-edge corrected

**Note:** UV = ultraviolet
## Table 3a: Indication Comparison

<table>
<thead>
<tr>
<th>Indication</th>
<th>Predicate Device</th>
<th>Subject Device</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Spherical</strong></td>
<td>For the correction of ametropia (myopia and hyperopia) in aphakic and non-aphakic persons with non-diseased eyes in powers from -20.00 to +20.00 diopters. The lenses may be worn by persons who exhibit astigmatism of 2.00 diopters or less that does not interfere with visual acuity.</td>
<td>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.</td>
</tr>
<tr>
<td><strong>Toric</strong></td>
<td>For the correction of ametropia (myopia and hyperopia) 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 -5.00 diopters.</td>
<td>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.</td>
</tr>
<tr>
<td><strong>Multifocal</strong></td>
<td>For the correction of refractive ametropia (myopia &amp; hyperopia) and emmetropia with presbyopia in aphakic and non-aphakic persons with non-diseased eyes in powers of -20.00 to +20.00 diopters and with add powers from +0.50 to +3.00 diopters. The lenses may be worn by persons who exhibit astigmatism of 2.00 diopters or less that does not interfere with visual acuity.</td>
<td>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 may have 0.75D or less of astigmatism.</td>
</tr>
<tr>
<td><strong>Multifocal-Toric</strong></td>
<td>N/A</td>
<td>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.</td>
</tr>
<tr>
<td><strong>UV Statement</strong></td>
<td>N/A</td>
<td>Contain a UV Blocker to help protect against transmission of harmful UV radiation to the cornea and into the eye.</td>
</tr>
</tbody>
</table>

*Note: UV = ultraviolet*
Table 3b: Wear/Replacement Schedule Comparison

<table>
<thead>
<tr>
<th>Wear/Replacement Schedule</th>
<th>Predicate Device</th>
<th>Subject Device</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>CooperVision (comfilcon A)</td>
<td>ACUVUE® (senofilcon C) Soft Contact Lens</td>
</tr>
<tr>
<td></td>
<td>The wearing and replacement schedules should be determined by the Eye Care Practitioner. Patients tend to over-wear the lenses initially. The Eye Care Practitioner should emphasize the importance of adhering to the initial maximum wearing schedule. Regular checkups, as determined by the eye care practitioner are also extremely important. CooperVision recommends that all Biofinity® lenses be discarded and replaced with a new lens on a frequent replacement basis. The eye care practitioner is encouraged to determine an appropriate lens replacement schedule based upon the response of the patient. The Eye Care Practitioner should determine the wearing and replacement schedule, based upon the patient’s history and their ocular examination, as well as the practitioner’s experience and clinical judgment.</td>
<td>The wearing schedule should be determined by the Eye Care Professional. Regular checkups, as determined by the Eye Care Professional, are also extremely important. Patients tend to over wear the lenses initially. The Eye Care Professional should emphasize the importance of adhering to the initial maximum wearing schedule. Maximum wearing time should be determined by the Eye Care Professional based upon the patient’s physiological eye condition, because individual response to contact lenses varies. Studies have not been completed to show that the lens is safe to wear during sleeping. When prescribed for daily wear (frequent replacement), it is recommended that the lenses be discarded and replaced with a new lens each month. However, the Eye Care Professional is encouraged to determine an appropriate lens replacement schedule based upon the response of the patient. When prescribed for daily disposable wear, the lenses should be discarded upon removal.</td>
</tr>
</tbody>
</table>
Nonclinical Performance Data

A series of in-vitro and in-vivo preclinical toxicology and biocompatibility tests were performed to assess the safety and effectiveness of the contact lens following the 1994 FDA Guidance Document for Daily Wear Contact Lenses. All nonclinical toxicology 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
  - Refractive Index
  - Water Content
  - Oxygen Permeability
  - Specific Gravity
  - Modulus
  - Tensile Strength
  - Elongation
  - Dynamic Contact Angle
  - Leachables

- Biocompatibility
  - Ocular Irritation (according to ISO 10993-10:2010)
  - Cytotoxicity (according to ISO 10993-5:2009)

- Solution Compatibility (according to ISO 11981:2009) and Preservative Uptake/Release (according to ISO 11986:2010)
  - Alexidine Dihydrochloride (Alexidine)
  - Polyhexamethylene Biguanide (PHMB)
  - Polyquaternium-1 (PQ-1)
  - Myristamidopropyl Dimethylamine (Aldox)

The results of the nonclinical testing on the ACUVUE® (senofilcon C) Contact Lens 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.
Clinical Performance Data

A three-month clinical study was conducted in the U.S. to demonstrate the safety and efficacy of the ACUVUE® (senofilcon C) Soft Contact Lens (test lens) by comparison with CooperVision (comfilcon A) contact lenses (control lens) when worn on a daily wear basis. The clinical study provided data to establish substantial equivalence with the predicate, control lens.

The study evaluated 221 subjects, 109 for the test lens and 112 for the control lens in a prospective, randomized, parallel group design. The primary safety and efficacy endpoints were slit lamp findings and visual acuity respectively. Additional variables were evaluated including keratometry changes, problems, symptoms and complaints, daily average wear time, adverse reactions, reasons for discontinuation, and the number and reasons for unscheduled lens replacements.

The clinical evaluation demonstrated similar overall performance in the clinically relevant areas of vision and health between the test ACUVUE® (senofilcon C) and control CooperVision (comfilcon A) lenses when worn under daily wear conditions.

Conclusions Drawn from the Nonclinical and Clinical Tests

Substantial Equivalence: Information presented in this Premarket Notification establishes that the ACUVUE® (senofilcon C) Soft Contact Lens is as safe and effective as the predicate device when used in accordance with the labeled directions for use and for the requested indication. Any differences that may exist between the senofilcon C Soft Contact Lens and the control lens do not adversely affect the safety and efficacy of the test lens when worn according to instructions.

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.