December 11, 2018

Marie Dutton
Senior Regulatory Affairs Specialist
5870 Stoneridge Drive
Suite 1
Pleasanton, CA 94588

Re: K181920
Trade/Device Name: Clariti 1 day (somofilcon A) Soft (Hydrophilic) Daily Disposable Contact Lens with UV Blocker
Regulation Number: 21 CFR 886.5925
Regulation Name: Soft (Hydrophilic) Contact Lens
Regulatory Class: Class II
Product Code: LPL, MVN
Dated: November 6, 2018
Received: November 7, 2018

Dear Marie Dutton:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

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 yours,

J. Angelo Green

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)*
K181920

Device Name
Clariti 1 day (somofilcon A) Soft (Hydrophilic) Daily Disposable Contact Lens with UV Blocker

Indications for Use *(Describe)*
The CLARITI 1 DAY (somofilcon A) Soft (hydrophilic) Daily Disposable Contact Lens with UV blocker is indicated for daily wear single use only for the correction of refractive ametropia (myopia and hyperopia) in phakic or aphakic persons with non-diseased eyes that may exhibit astigmatism up to 2.00 Diopters that does not interfere with visual acuity.

The CLARITI 1 DAY TORIC (somofilcon A) Soft (hydrophilic) Daily Disposable Contact Lens with UV blocker is indicated for daily wear single use only for the optical correction of refractive ametropia (myopia and hyperopia) in phakic or aphakic persons with non-diseased eyes that may exhibit astigmatism up to 10.00 Diopters.

The CLARITI 1 DAY MULTIFOCAL (somofilcon A) Soft (hydrophilic) Daily Disposable Contact Lens with UV blocker is indicated for daily wear single use only for the optical correction of refractive ametropia (myopia and hyperopia) and/or presbyopia in phakic or aphakic persons with non-diseased eyes that may require a reading addition of +3.00 Diopters or less and may exhibit astigmatism up to 1.50 Diopters or less.

The CLARITI 1 DAY MULTIFOCAL TORIC (somofilcon A) Soft (hydrophilic) Daily Disposable Contact Lens with UV blocker is indicated for daily wear single use only for the optical correction of refractive ametropia (myopia and hyperopia) and/or presbyopia in phakic or aphakic persons with non-diseased eyes that may exhibit astigmatism up to 10.00 Diopters and require a reading addition of +3.00 Diopters or less.

The Clariti 1 Day (somofilcon A) Soft (hydrophilic) Contact Lenses are indicated for daily wear single use only. The lenses are to be discarded upon removal; therefore, no cleaning or disinfection is required.

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

I. SUBMITTER:

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Date Prepared:
November 6, 2018

II. DEVICE:

Name of Device:	Clariti 1 day (somofilcon A) Soft (Hydrophilic) Daily Disposable Contact Lens with UV Blocker
Common Name:	Soft (hydrophilic) Contact Lens
Classification Name:	Lens, Contact, (Disposable) [21 CFR 886.5925 (b) (1)]
Regulatory Class:	II
Product Code:	MVN, LPL
Classification Panel:	Ophthalmic

III. PREDICATE DEVICE:

Clariti 1 day (somofilcon A) Soft (Hydrophilic) Daily Disposable Contact Lens with UV Blocker, K130331

IV. DEVICE DESCRIPTION:

The device description for the subject device and predicate Clariti 1 day (somofilcon A) device is identical. The Clariti 1 day (somofilcon A) Soft (Hydrophilic) Daily Disposable Contact Lens with UV Blocker is available as sphere lens, toric lens, multifocal lens, and multifocal toric lens.

In its hydrated state, Clariti 1 day (somofilcon A) Soft (hydrophilic) Daily Disposable Contact Lens with UV Blocker when placed on the cornea acts as a refracting media to focus light rays on the retina.

Clariti 1 day (somofilcon A) Soft (hydrophilic) Contact Lenses for Daily Wear Single Use are a hydrophilic co-polymer of silicone containing monomers and hydrophilic monomers which is cross-linked with tetraethyleneglycol dimethacrylate and di-functional methacryloxypropyl-terminated poly(dimethylsiloxane).

When hydrated the lens consists of 44.0% somofilcon A and 56.0% water by weight of saline immersed in normal saline. A benzophenone UV absorbing monomer is used in the contact lens to help protect against transmission of harmful UV radiation and Clariti 1 day (somofilcon A) Soft contact lenses help protect against transmission of harmful UV radiation to the cornea and into the eye.

The average transmittance characteristics are less than 5% in the UVB range of 280 to 315nm and less than 50% in the UVA range of 316-380nm.

The lens has a hemispherical flexible shell, which covers the cornea and a portion of the adjacent sclera, with the following dimensions:

- Chord Diameter: 13.0mm to 15.5mm
- Centre Thickness: 0.03mm to 0.50mm
- Base Curve: 7.5mm to 9.30mm
- Powers: -20.00 DS to +20.00 DS
- Toric Cylinder options: -0.75, -1.25, -1.75 and -2.25
- Toric Axis options: 10° to 180° (10° steps)
- Multifocal Add:

  Lens “LOW” = “low” for spectacle near ADD lens (Max +2.25 ADD)
  Lens “HIGH” = “high” for spectacle near ADD lens (+2.50 ADD or greater)

The physical/optical properties of the lenses are:

- Refractive Index: 1.4003
- %Transmittance @ 590nm: 98.13
- %Transmittance @ 280-315nm: 0.71
- %Transmittance @ 316-380nm: 20.62
- Surface Character: Hydrophilic
- Water Content: 56%
- Oxygen Permeability (DK): 60×10^{-11} (cm^2/sec) (ml O_2/ml x mmHg) at 35°C (Fatt Method for determination of oxygen permeability)
- Specific Gravity: 1.17

V. INDICATIONS FOR USE:

The indications for use statement for the subject device and predicate Clariti 1 day (somofilcon A) device is identical.

Lens Design	Indication
Sphere	The **CLARITI 1 DAY** (somofilcon A) Soft (hydrophilic) Daily Disposable Contact Lens with UV blocker is indicated for daily wear single use only for the correction of refractive ametropia (myopia and hyperopia) in phakic or aphakic persons with non-diseased eyes that may exhibit astigmatism up to 2.00 Diopters that does not interfere with visual acuity.
Toric	The **CLARITI 1 DAY TORIC** (somofilcon A) Soft (hydrophilic) Daily Disposable Contact Lens with UV blocker is indicated for daily wear single use only for the optical correction of refractive ametropia (myopia and hyperopia) in phakic or aphakic persons with non-diseased eyes that may exhibit astigmatism up to 10.00 Diopters.
Multifocal	The **CLARITI 1 DAY MULTIFOCAL** (somofilcon A) Soft (hydrophilic) Daily Disposable Contact Lens with UV blocker is indicated for daily wear single use only for the optical correction of refractive ametropia (myopia and hyperopia) and/or presbyopia in phakic or aphakic persons with non-diseased eyes that may require a reading addition of +3.00 Diopters or less and may exhibit astigmatism up to 1.50 Diopters or less.
Multifocal Toric	The **CLARITI 1 DAY MULTIFOCAL TORIC** (somofilcon A) Soft (hydrophilic) Daily Disposable Contact Lens with UV blocker is indicated for daily wear single use only for the optical correction of refractive ametropia (myopia and hyperopia) and/or presbyopia in phakic or aphakic persons with non-diseased eyes that may exhibit astigmatism up to 10.00 Diopters and require a reading addition of +3.00 Diopters or less.

The Clariti 1 day (somofilcon A) Soft (hydrophilic) Contact Lenses are indicated for daily wear single use only. The lenses are to be discarded upon removal; therefore, no cleaning or disinfection is required.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE:

The technological principle for both the subject and predicate device somofilcon A soft (hydrophilic) contact lenses with UV blocker is identical. The subject and predicate device are based on the same technological elements. The two technological differences that exist between the subject and predicate device consist of the addition of 4,4'-Diallyoxyl benzophenone (DAB) and the change from borate to phosphate buffered packaging solution. A comparison of the technological characteristics of the subject device with the predicate device is provided in the table below.

For the technological difference of the addition of DAB, performance data was provided to demonstrate that the subject device lens material is equivalent to the currently marketed predicate device lens material. Additionally, there is no change to the USAN name of the device because additives such as UV absorbers are excluded for the purpose of nomenclature.

For the technological difference of the change from borate to phosphate buffered packaging solution, performance data was provided to ensure compatibility of the contact lens with the lens storage solution that comes into direct contact with the contact lens and to ensure that the changes in the packaging material has not compromised the sterility or stability of the contact lens for the labeled expiration date. Additionally, the requirements of the procedure for implementing changes in packaging materials, specifically the types of buffers utilized in lens packaging solutions or addition of buffers to saline solutions (e.g., borate to phosphate buffer), from the Premarket Notification [510(k)] Guidance Document for Daily Wear Contact Lenses, May 12, 1994 amended June 28, 1994 were met.

Technology/Material Comparison		
	Predicate Device	**Subject Device**
Product Name	Clariti 1 day (somofilcon A) Soft (Hydrophilic) Daily Disposable Contact Lens with UV Blocker	Same
Material USAN Name	somofilcon A	Same
510(k) Number	K130331	K181920
FDA Category (Group)	Materials having a Dk greater than 40 Dk units (using mmHg) and having a Dk greater than that expected based on the materials' water content alone (Group V)	Same
Manufacturing Method	Cast Molding	Same
Wearing and Replacement Schedule	Daily Wear Single Use	Same
Sterilization	Moist Heat	Same
Packaging Materials	Injection molded polypropylene blisters covered by aluminum foil laminate and blister strips are packed into printed cartons	Same
Packaging Solution	Borate Buffered Saline Solution containing 0.005% w/v Poloxamer 407	Phosphate Buffered Saline Solution containing 0.020% w/v Poloxamer 407
Blue Visibility Tint	No	Same
Tint	None	Same
UV Blocker	UV416	UV416 and DAB

VII. PERFORMANCE DATA:

The performance specifications/parameters for both the subject and predicate device Clariti 1 day (somofilcon A) contact lenses with UV blocker are identical and provided in the comparison table below.

Performance Specifications/Parameters Comparison		
	Predicate Device Clariti 1 day (somofilcon A) K130331	**Subject Device Clariti 1 day (somofilcon A) K181920**
Water Content (%)	56	Same
Refractive Index	1.401	Same
Oxygen Permeability (Dk @ 35°C)	60×10^{-11} [(cm^2/sec) x (ml O_2)/(ml x mm Hg)]	Same
Base Curve (mm)	8.6	Same
Diameter (mm)	14.0	Same
Light Transmittance (%)	>95	Same
Modulus (MPa)	≥0.3	Same
Tensile Strength (MPa)	≥0.4	Same
Elongation to Break (%)	≥100	Same
Surface Treatment	No	Same
Center Thickness (mm)	Varies with power	Same
Power Range (D)	-20.00 to + 20.00	Same

The following performance data were provided in support of the substantial equivalence determination. All tests were conducted in accordance with the GLP regulation (21 CFR Part 58) or according to valid scientific protocols.

Biocompatibility testing:

The biocompatibility evaluation for the subject Clariti 1 day (somofilcon A) device was conducted in accordance with the Guidance for Industry and Food and Drug Administration Staff entitled Use of International Standard ISO 10993-1, "Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process," June 16, 2016 and the Premarket Notification [510(k)] Guidance Document for Daily Wear Contact Lenses, May 12, 1994 amended June 28, 1994. The battery of testing included the following tests:

- Cytotoxicity per ISO 10993-5:2009
- Irritation per ISO 10993-10:2010 and ISO 9394:2012
- Systemic Toxicity per ISO 10993-11:2006 and ISO 10993-1:2009
- Sensitization per ISO 10993-10:2010

Performance testing – bench:
The performance testing for the subject Clariti 1 day (somofilcon A) device was conducted in accordance with the Premarket Notification [510(k)] Guidance Document for Daily Wear Contact Lenses, May 12, 1994 amended June 28, 1994. The battery of testing included the following. Each test was conducted according to the ANSI, ISO, and/or ASTM standard indicated:

- Light transmittance per ANSI Z80.20-2010 and ISO 18369-3:2006
- Oxygen permeability per ISO 18369-4:2006
- Water content per ISO 18369-4:2006
- Refractive index per ISO 16369-4:2006
- Mechanical properties per ANSI Z80.20-2010 and ASTM D1708-13
- Lens specification per ANSI Z80.20-2010, ISO 18369-2:2012, and ISO 18369-3:2006
- Specific gravity per ISO 1183-1:2012
- Contact angle per ANSI Z80.20-2010
- Total extractables per ISO 18369-4:2006
- Non-polymeric residuals in lens and packaging solution, solvents chosen per ISO 18369-4:2006

Clinical testing:
Data provided in this 510(k) is sufficient to adequately characterize the modified subject Clariti 1 day (somofilcon A) device in terms of its physical/chemical/optical, and toxicological performance characteristics when compared to the predicate. The results are equivalent determining that additional clinical performance data was not required to complete the substantial equivalent determination. Additionally, the technical characteristics and manufacturing and sterilization processes of the subject lens are equivalent to somofilcon A contact lens currently marketed by CooperVision; therefore, it was confirmed no clinical data is required.

VIII. CONCLUSIONS:

Conclusive evidence was provided to demonstrate that the subject device lens material is equivalent to the currently marketed predicate device lens material through the statistical analysis of the physiochemical properties, especially water content, oxygen permeability, modulus, and toughness of the lens. Therefore, there is no change to the USAN name of the device. Based on this performance testing and the fact that the subject device has the same manufacturing process as the marketed predicate device lens, clinical performance data was not required to be submitted in this 510(k). There were no differences in physiochemical properties, especially water content, oxygen permeability, modulus, and toughness of the lens. The performance testing demonstrates that the subject Clariti 1 day (somofilcon A) device performs comparably to the predicate Clariti 1 day (somofilcon A) device that is currently marketed for the same intended use.

The modifications made to the subject Clariti 1 day (somofilcon A) device did not have a significant impact on the performance characteristics of the 510(k) cleared predicate device. There is sufficient data provided in this 510(k) to adequately characterize the modified lens in terms of its physical/chemical/optical, and toxicological performance characteristics when compared to the previously cleared lens. Results of the pre-clinical testing (physical/chemical/optical and toxicological data) are sufficient to support the claim and clinical performance data are not needed to assess effects of the new characteristics.