January 25, 2024

CooperVision, Inc.
Sahana Rajashekar
Regulatory Affairs Specialist
6101 Bollinger Canyon Road, Suite 500
San Ramon, CA 94583

Re: K234127
Trade/Device Name: Clariti 1 Day Multifocal (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: December 28, 2023
Received: December 28, 2023

Dear Sahana Rajashekar:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 -S

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

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)*
K234127

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

Indications for Use *(Describe)*
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.

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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K234127

510(k) Summary

Date Prepared: Jan 24, 2024

Submitter: CooperVision, Inc.
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Device Identification:
1. Trade Name: Clariti 1 Day Multifocal (somofilcon A) Soft (Hydrophilic) Daily Disposable Contact Lens with UV Blocker
2. Common Name: Soft (hydrophilic) Contact Lens
3. Classification Name: Lens, Contact, (Disposable)/MVN;
Product Code: Lenses, Soft Contact, Daily Wear/LPL
4. Classification Regulation: Class II [21 CFR 886.5925 (b) (1)]
5. Classification Panel: Division of Ophthalmic and Ear, Nose and Throat Devices

Predicate Device: Clariti 1 Day Multifocal (somofilcon A) Soft (Hydrophilic) Daily Disposable Contact Lens with UV Blocker (K181920)

Description of Device:

Clariti 1 Day Multifocal (somofilcon A) Soft (Hydrophilic) Daily Disposable Contact Lens with UV Blocker is a hydrophilic co-polymer of silicone containing monomers and hydrophilic monomers which is cross-linked with tetraethyleneglycol dimethacrylate and difunctional 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 Multifocal (somofilcon A) Soft (Hydrophilic) Daily Disposable Contact Lens with UV Blocker 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
- Multifocal ADD:

Multifocal 3 ADD (Binocular Progressive System) Power Range:
LOW = (+0.75D to +1.25D)
MED = (+1.50D to +1.75D)
HIGH = (+2.00D to +2.50D)

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 x 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

Indications for use:
The indications for use statement for the subject device and predicate device is identical.

Lens Design	Indication
Multifocal	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.

Comparison of technological characteristics with the predicate device:
The technological characteristics of the subject device and the predicate device are compared in the table below.

Technology/Material Comparison		
	Predicate Device	**Subject Device**
Product Name	Clariti 1 Day Multifocal (somofilcon A) Soft (Hydrophilic) Daily Disposable Contact Lens with UV Blocker	Same
Material USAN Name	somofilcon A	Same
510(k) Number	K181920	K234127
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
Indications for Use	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.	Same
Manufacturing Method	Cast Molding	Same
Wearing and Replacement Schedule	Daily Wear Single Use	Same
Sterilization Method	Moist Heat	Same

Technology/Material Comparison		
	Predicate Device	**Subject Device**
Packaging Materials	Injection molded polypropylene blisters covered by aluminum foil laminate and blister strips are packed into printed cartons	Same
Packaging Solution	Phosphate Buffered Saline Solution containing 0.005% w/v Poloxamer 407	Same
Blue Visibility Tint	No	Same
Tint	None	Same
UV Blocker	UV416	Same
Design	2ADD (Low and High)	3ADD (Low, Medium, and High)

Performance data:
Results from non-clinical studies were provided in support of the substantial equivalence determination.

Performance testing:
In accordance with the Premarket Notification [510(k)] Guidance Document for Daily Wear Contact Lenses, issued June 27, 1994, the following performance tests were conducted according to BS EN ISO 18369-2:2017 and BS EN ISO 18369-4:2017:

- Water content
- Dimensional/optical parameters

All tests were conducted in accordance with the GLP regulation (21 CFR Part 58) or according to valid scientific protocols.

Biocompatibility testing:
No biocompatibility testing was required as there are no changes to the lens formulation or manufacturing method.

Conclusion

This 510(k) is submitted in accordance with the Premarket Notification [510(k)] Guidance Document for Daily Wear Contact Lenses, issued June 27, 1994, for a change in the lens design. Because the predicate device lens material, performance testing specifications, primary packaging materials and packaging solution are identical to the subject device, non-clinical data presented are adequate to support substantial equivalence. Therefore, the subject Clariti 1 Day Multifocal (somofilcon A) Soft

(Hydrophilic) Daily Disposable Contact Lens with UV Blocker is considered as safe and as effective as the predicate device.