March 23, 2020

CooperVision, Inc.
Ms. Marie Dutton
Senior Regulatory Affairs Specialist
5870 Stoneridge Drive, Suite 1
Pleasanton, CA 94588

Re: K191763
Trade/Device Name: MyDay (stenfilcon A) Soft (Hydrophilic) Daily Disposable Contact Lens
Regulation Number: 21 CFR 886.5925
Regulation Name: Soft (Hydrophilic) Contact Lens
Regulatory Class: Class II
Product Code: LPL, MVN
Dated: February 24, 2020
Received: February 25, 2020

Dear Ms. 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/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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K191763

Device Name

MyDay (stenfilcon A) Soft (Hydrophilic) Daily Disposable Contact Lens

Indications for Use *(Describe)*

MyDay (stenfilcon A) ASPHERE Soft Contact lenses are indicated 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.

MyDay (stenfilcon A) TORIC Soft Contact lenses are indicated for the correction of ametropia (myopia or hyperopia with astigmatism) 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 -10.00 diopters.

MyDay (stenfilcon A) MULTIFOCAL Soft Contact lenses are indicated for the correction of refractive ametropia (myopia and hyperopia) and emmetropia with presbyopia in aphakic and non-aphakic persons with non-diseased eyes. The lenses may be worn by persons who exhibit astigmatism of -2.00 diopters or less that does not interfere with visual acuity.

MyDay (stenfilcon A) MULTIFOCAL TORIC Soft Contact lenses are indicated for the optical correction of distance and near vision in presbyopic phakic or aphakic persons with non-diseased eyes who may have -10.00 diopters of astigmatism 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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510(k) Summary

I. SUBMITTER:

CooperVision, Inc.
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Contact Person:
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Senior Regulatory Affairs Specialist
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Date Prepared:
June 28, 2019

II. DEVICE:

Trade Name:	MyDay (stenfilcon A) Soft (Hydrophilic) Daily Disposable Contact Lens
Common Name:	Soft (hydrophilic) Contact Lens
Classification Name:	Lens, Contact, (Disposable) [21 CFR 886.5925 (b) (1)]
Regulatory Class:	II
Product Code:	LPL, MVN
Classification Panel:	Ophthalmic

III. PREDICATE DEVICE:

The predicate device is CooperVision's MyDay (stenfilcon A) Soft (Hydrophilic) Daily Disposable Contact Lens, submitted as SUS (stenfilcon A) Soft (hydrophilic) Contact Lenses for Single Use Daily Wear under 510(k) K131378 and received FDA clearance on August 30, 2013.

IV. DEVICE DESCRIPTION:

The device description for the subject device and the predicate device is identical.

MyDay (stenfilcon A) Soft (Hydrophilic) Daily Disposable Contact Lens is available as an Asphere, Toric, Multifocal, and Multifocal Toric lens designs.

The MyDay material, stenfilcon A, is primarily a random copolymer of polydimethylsiloxane methacrylate and vinylmethyl acetamide. The UV blocker used is a benzotriazolyl methacrylate. The lenses have a blue tint which is added to make the lens more visible for handling. The lenses also contain a UV absorbing monomer which is used to block UV radiation.

When placed on the cornea in its hydrated state, the MyDay Soft (Hydrophilic) Contact Lens acts as a refracting medium to focus light rays on the retina.

MyDay (stenfilcon A) contact lens parameters are:

- Chord Diameter: 13.0 mm to 15.5mm
- Base Curve: 8.4 ± 0.5 mm and 8.7 ± 0.5 mm
- Center Thickness: 0.08 mm to 0.218 mm (varies with power)
- Powers: -20.00D to +20.00D
- Cylinder Powers: -0.25D to -10.00D
- Axis: 0° to 180° in 10° increments
- Add Power Range: +0.50 to +4.00

The physical/optical properties of the lens are:

- Specific Gravity: 1.033
- Refractive Index: 1.401
- Light Transmittance: 96%
- Surface Character: Hydrophilic
- Water Content: 54%
- Oxygen Permeability: $80x10^{-11}$ $[(cm^2/sec)x(ml\ O_2)/(ml\ x\ mm\ Hg)]$

V. INDICATIONS FOR USE:

There is no difference between the subject device and the predicate device with respect to indications and intended use.

MyDay (stenfilcon A) ASPHERE Soft Contact lenses are indicated 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.

MyDay (stenfilcon A) TORIC Soft Contact lenses are indicated for the correction of ametropia (myopia or hyperopia with astigmatism) 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 -10.00 diopters.

MyDay (stenfilcon A) MULTIFOCAL Soft Contact lenses are indicated for the correction of refractive ametropia (myopia and hyperopia) and emmetropia with presbyopia in aphakic and non-aphakic persons with non-diseased eyes. The lenses may be worn by persons who exhibit astigmatism of -2.00 diopters or less that does not interfere with visual acuity.

MyDay (stenfilcon A) MULTIFOCAL TORIC Soft Contact lenses are indicated for the optical correction of distance and near vision in presbyopic phakic or aphakic persons with non-diseased eyes who may have -10.00 diopters of astigmatism or less.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE:

The technological principle for both the subject and the predicate device is identical. The subject and predicate device are based on the same technological elements. The only technological difference that exists between the subject and predicate device is the addition of 100 ppm Epsilon-Polylysine (also known as e-polylysine or e-PL) to the blister packing solution formulation.

The e-PL is being added to the packaging solution as a preservative. Changes to the labeling are being made to reflect the addition of e-PL to the packaging solution.

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	MyDay (stenfilcon A) Soft (Hydrophilic) Daily Disposable Contact Lens	MyDay (stenfilcon A) Soft (Hydrophilic) Daily Disposable Contact Lens (with e-PL in the packaging solution)
Material USAN Name	stenfilcon A	Same
510(k) Number	K131378	TBD – Current Submission
FDA Category (Group)	Silicone Hydrogel	Same
Manufacturing Method	Molded	Same
Sterilization	Moist Heat	Same
Packaging Materials	Injection molded polypropylene blisters covered by aluminum foil laminate; blister strips are packed into printed cartons	Same
Packaging Solution	Phosphate Buffered Saline Solution with Tween	Phosphate Buffered Saline Solution with Tween and 100 ppm e-PL
Visibility Tint	Reactive Blue #246 (RB246)	Same
UV Blocker	Norbloc	Same

VII. PERFORMANCE DATA:

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

Performance testing - bench:

In accordance with the Premarket Notification [510(k)] Guidance Document for Daily Wear Contact Lenses, issued on May 12, 1994 and amended June 28, 1994, the following battery of physicochemical testing was performed. All tests were conducted in accordance with the GLP regulation (21 CFR Part 58) or according to valid scientific protocols. Each test was conducted according to the ANSI, ISO, and/or ASTM standard indicated:

- Water content per ISO18369-2:2012 and ISO 18369-4:2006
- Refractive index per ISO 18369-2:2012 and ISO 16369-4:2006
- Light transmittance per ISO 18369-2:2012 and ISO 18369-3:2006
- Non-polymeric residuals in lens and packaging solution per ISO 18369-4:2006
- Total extractable per ANSI Z80.20-2010 and ISO 18369-4:2006
- Contact angle per ANSI Z80.20-2010
- Mechanical properties per ANSI Z80.20-2010 and ASTM D1708-02a

Additionally, preservative efficacy testing (PET) per ISO 14730:2014, analytical testing (uptake and release) per ISO 11986:2010, and in-vitro microbiological testing (lens handling) were performed to support the function of e-PL as that of a preservative.

Biocompatibility testing:

In accordance with the Premarket Notification [510(k)] Guidance Document for Daily Wear Contact Lenses, issued on May 12, 1994 and amended June 28, 1994 and with the GLP regulation (21 CFR Part 58), the following battery of biocompatibility testing was performed:

- Cytotoxicity per ISO 10993-5:2009
- Systemic Toxicity per ISO 10993-11:2006
- Sensitization per ISO 10993-10:2010
- Irritation per ISO 10993-10:2010
- Irritation (22 Day) per ISO 9394:2012

Clinical testing:
Data provided in this 510(k) is sufficient to adequately characterize the subject device in terms of its physical/mechanical/optical and toxicological performance characteristics when compared to the predicate device. The results are equivalent, determining that additional clinical performance data was not required to complete the substantial equivalence determination. Additionally, the technical characteristics and manufacturing and sterilization processes of the subject lens are equivalent to MyDay (stenfilcon A) contact lens currently marketed by CooperVision; therefore, it was confirmed that 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 physical/mechanical/optical properties of the lens. Based on the 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). The performance testing demonstrates that the subject device is as safe, as effective, and performs as well as the predicate device.