



September 6, 2018

Gelflex Laboratories
% Bret Andre
Principal Consultant
EyeReg Consulting, Inc.
6119 Canter Ln
West Linn, OR 97068

Re: K181558

Trade/Device Name: Sofclear Enhance (methafilcon A) Daily Wear Contact Lens, Sofclear Colors (methafilcon A) Daily Wear Contact Lens, Sofclear Comfort (methafilcon A) Daily Wear Contact Lens

Regulation Number: 21 CFR 886.5925

Regulation Name: Soft (hydrophilic) contact lens

Regulatory Class: Class II

Product Code: LPL, MVN

Dated: August 6, 2018

Received: August 9, 2018

Dear Bret Andre:

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 and Part 809); 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

Indications for Use

510(k) Number (if known)

K181558

Device Name

Sofclear Enhance (methafilcon A) Daily Wear Contact Lens; Sofclear Colors (methafilcon A) Daily Wear Contact Lens; Sofclear Comfort (methafilcon A) Daily Wear Contact Lens

Indications for Use (Describe)

The Sofclear Enhance, Colors, and Comfort (methafilcon A) contact lenses for daily wear are indicated for the correction of refractive error in aphakic and not aphakic persons with non-diseased eyes with myopia or hyperopia. The lens may be worn by persons who exhibit refractive astigmatism of 0.75 diopters or less where the astigmatism does not interfere with visual acuity. The lens is available clear or tinted and may be used to enhance or alter the apparent color of the eye.

Daily wear replacement schedules may vary from patient to patient and should be decided by eye care practitioners in consultation with their patients.

Eye care practitioners may prescribe any of the above lenses for frequent/planned replacement wear, with cleaning disinfection and scheduled replacement. When prescribed for frequent/planned replacement wear, the lens may be disinfected using a chemical disinfecting system.

Eye care practitioners may prescribe any of the above lenses for single use daily disposable wear. When prescribed for daily disposable wear the lens is to be discarded after each 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.

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510 (k) SUMMARY OF SAFETY AND EFFECTIVENESS

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is: K181558

I. SUBMITTER

Date Prepared: June 4th, 2018

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Consultant: Bret Andre
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6119 Canter Ln.
West Linn, OR 97068
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II. DEVICE

Trade Name: **Sofclear Enhance (methafilcon A) Daily Wear Contact Lens**
Sofclear Colors (methafilcon A) Daily Wear Contact Lens
Sofclear Comfort (methafilcon A) Daily Wear Contact Lens

Common Name: Contact Lens, Daily Wear

Classification Name: Soft (hydrophilic) Contact Lens (21 CFR 886.5925)

Regulatory Class: Class II

Product Code: LPL; MVN

Purpose of 510(k) Submission:

~ New Device ~

III. PREDICATE DEVICE

The **Sofclear Enhance, Colors, and Comfort (methafilcon A) Daily Wear Contact Lenses** are substantially equivalent to the following predicate device(s):

- **“55 UV (methafilcon A) Soft (Hydrophilic) Contact Lens for Daily Wear”**
Optical Connection, Inc.
510(k) number; **K051095**
Primary Predicate
- **“Focus Softcolors (vifilcon A) Soft (Hydrophilic) Contact Lenses”**
Alcon Laboratories, Inc.
PMA number; **P820021 (S025)**
Reference Predicate
- **“Frequency Colors (methafilcon A)”**
By Coopervision, Inc.
510(k) number; K001090
Reference Predicate

IV. DEVICE DESCRIPTION**Sofclear Enhance (methafilcon A) Daily Wear Contact Lens**

The **Sofclear Enhance (methafilcon A) Daily Wear Contact Lenses** are hemispherical shells with molded spherical base curves and molded front surfaces. The hydrophilic characteristics allow aqueous solutions to enter the lens. The lenses are fabricated from methafilcon A, which is a hydrophilic co-polymer of 2-Hydroxyethyl methacrylate (2-HEMA) and methacrylic acid, cross-linked with ethylene glycol dimethacrylate (EGDMA), plus an initiator. The co-polymer consists of 45% methafilcon A and 55% water by weight when immersed in saline solution. The (methafilcon A) name has been adopted by the United States Adopted Names Council (USAN).

The **Sofclear Enhance (methafilcon A) Daily Wear Contact Lenses** are available tinted to enhance or alter the apparent color of the eye. The lenses are tinted with one or a combination of one or more of the following ‘listed’ color additives:

Color Additive	Listing
Reactive Blue 21	21 CFR § 73.3127
Reactive Blue 19	21 CFR § 73.3127
Reactive Yellow 86	21 CFR § 73.3121

The lenses are processed to incorporate the ‘listed’ color additives and contain only the amount of the



510(k) Premarket Notification

additive needed to accomplish the intended coloring effect. When producing the lenses, the manufacturing process alters and/or changes the specifications to the clear contact lens by binding the reactive color dye(s) into the contact lens material in a location that covers the iris and pupil. The color additives used are not removed by lens handling and cleaning/disinfecting procedures. Except for affecting the amount of light transmittance through the lens, the coloring process does not alter the original characteristics of the lens.

Sofclear Colors (methafilcon A) Daily Wear Contact Lens

The **Sofclear Colors (methafilcon A) Daily Wear Contact Lenses** are hemispherical shells with molded spherical base curves and molded front surfaces. The hydrophilic characteristics allow aqueous solutions to enter the lens. The lenses are fabricated from methafilcon A, which is a hydrophilic co-polymer of 2-Hydroxyethyl methacrylate (2-HEMA) and methacrylic acid, cross-linked with ethylene glycol dimethacrylate (EGDMA), plus an initiator. The co-polymer consists of 45% methafilcon A and 55% water by weight when immersed in saline solution. The (methafilcon A) name has been adopted by the United States Adopted Names Council (USAN).

The **Sofclear Colors (methafilcon A) Daily Wear Contact Lenses** are available printed to enhance or alter the apparent color of the eye. The lenses are printed with one or a combination of one or more of the following 'listed' color additives:

Color Additive	Listing
Red Iron Oxide	21 CFR § 73.3125
Violet 23	21 CFR § 73.3107
Titanium Dioxide	21 CFR § 73.3126
Chromium Oxide Green	21 CFR § 73.3111
Blue 36	21 CFR § 73.3110a

The lenses are processed to incorporate the 'listed' color additives and contain only the amount of the additive needed to accomplish the intended coloring effect. When producing the lenses, the manufacturing process alters and/or changes the specifications to the clear contact lens by pad-printing the color pigment(s)—entrapping them in the interpenetrating network of the contact lens material in a location that corresponds to the iris. The color pigments used are not removed by lens handling and cleaning/disinfecting procedures. Except for affecting the amount of light transmittance through the lens, the coloring process does not alter the original characteristics of the lens. The printing pattern has a minimum clear pupil diameter of 6.5 mm when the lens is hydrated.

Sofclear Comfort (methafilcon A) Daily Wear Contact Lens

The **Sofclear Comfort (methafilcon A) Daily Wear Contact Lenses** are hemispherical shells with molded spherical base curves and molded front surfaces. The hydrophilic characteristics allow aqueous solutions to enter the lens. The lenses are fabricated from methafilcon A, which is a hydrophilic co-polymer of 2-Hydroxyethyl methacrylate (2-HEMA) and methacrylic acid, cross-linked with ethylene glycol dimethacrylate (EGDMA), plus an initiator. The co-polymer consists of 45% methafilcon A and 55% water by weight when immersed in saline solution. The (methafilcon A) name has been adopted by the United States Adopted Names Council (USAN).

The **Sofclear Comfort (methafilcon A) Daily Wear Contact Lenses** include a tint (1,4-Bis[4-(2-methacryloxyethyl)phenylamino]-9,10-anthraquinone) in the composition of the lens for ease of handling and visibility.

The **Sofclear Enhance, Colors, and Comfort (methafilcon A) Daily Wear Contact Lenses** incorporate a UV absorbing monomer. The lenses block >88% in the UVB range (280nm - 315nm), and >68% in the UVA range (316nm - 380nm).

The **Sofclear Enhance, Colors, and Comfort (methafilcon A) Daily Wear Contact Lenses** will be manufactured in the spherical design configuration. The material properties and available parameters of the finished lenses are as follows:

Parameter	Range	Tolerance*
Chord Diameter	11.00 mm to 15.00 mm	±0.20 mm
Center Thickness	0.05 mm to 0.210 mm	When ≤ 0.10 mm → ±0.010 mm + 10% When > 0.10 mm → ±0.015 mm + 5%
Base Curve	7.00 mm to 10.0 mm	±0.20 mm
Back Vertex Power (F'v)	+20.00D to -20.00D (in 0.25D steps)	When 0.00 < F'v ≤ 10.00 D → ±0.25 D When 10.00 < F'v ≤ 20.00 D → ±0.50 D
Surface Appearance	-	Lenses should be clear with no surface defect
Oxygen Permeability (x 10⁻¹¹(cm²/sec)(mlO₂)/(ml x mmHg))	20.4	±20%
Light Transmission (@ 380-780nm)	>97%	±5%
Ultraviolet Radiation Transmittance	< 12 % T _{UVB} < 32 % T _{UVA}	T _{UVB} (280 to 315 nm) < 0.05T _V T _{UVA} (316 to 380 nm) < 0.50T _V
Water Content	55%	±2%
Refractive Index	1.405 (hydrated)	±0.005

*ANSI Z80.20, Ophthalmics – Contact Lenses – Standard Terminology, Tolerances, Measurements And Physicochemical Properties (2010)

V. INDICATIONS FOR USE

The **Sofclear Enhance, Colors, and Comfort (methafilcon A)** contact lenses for daily wear are indicated for the correction of refractive error in aphakic and not aphakic persons with non-diseased eyes with myopia or hyperopia. The lens may be worn by persons who exhibit refractive astigmatism of 0.75 diopters or less where the astigmatism does not interfere with visual acuity. The lens is available clear or tinted and may be used to enhance or alter the apparent color of the eye.

Daily wear replacement schedules may vary from patient to patient and should be decided by eye care practitioners in consultation with their patients.

Eye care practitioners may prescribe any of the above lenses for frequent/planned replacement wear, with cleaning disinfection and scheduled replacement. When prescribed for frequent/planned replacement wear, the lens may be disinfected using a chemical disinfecting system.

Eye care practitioners may prescribe any of the above lenses for single use daily disposable wear. When prescribed for daily disposable wear the lens is to be discarded after each removal.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH PREDICATE DEVICE

The **Sofclear Enhance, Colors, and Comfort (methafilcon A) Daily Wear Contact Lenses** are substantially equivalent to 55 UV (methafilcon A) Soft (Hydrophilic) Contact Lens for Daily Wear (cleared under K051095) in terms of the following:

- USAN contact lens material (methafilcon A)
- Intended use – daily wear contact lenses
- Actions
- Indications for use
- Cast molded production method
- FDA Group 4 (>50% H₂O, ionic polymer)
- FDA classification – Soft (hydrophilic) Contact Lens (21 CFR 886.5925)

The **Sofclear Enhance, Colors, and Comfort (methafilcon A) Daily Wear Contact Lenses** are substantially equivalent to Focus Softcolors (Vifilcon A) Soft (Hydrophilic) Contact Lenses (approved under PMA - P820021 S025) in terms of the following:

- Contact lens tinting method – Enhance contact lenses

The **Sofclear Enhance, Colors, and Comfort (methafilcon A) Daily Wear Contact Lenses** are substantially equivalent to Frequency Colors (methafilcon A) (cleared under K001090) in terms of the following:

- Pad-printing contact lens tinting method

The following matrix illustrates the production method, lens function and material characteristics of the **Sofclear Enhance, Colors, and Comfort (methafilcon A) Daily Wear Contact Lenses**, as well as the predicate devices.

Substantial Equivalence Matrix

	Sofclear Enhance, Colors, & Comfort (Subject Device)	Optical Connection Inc. 55 UV (K051095)	Alcon Focus Softcolors (P820021 S025)	Coopervision Frequency Colors (K001090)
Indications for Use	Indicated for daily wear for the correction of refractive error in aphakic and not aphakic persons with non-diseased eyes with myopia or hyperopia.	Indicated for daily wear for the correction of refractive error in aphakic and not aphakic persons with non-diseased eyes with myopia or hyperopia.	Indicated for daily wear for the correction of refractive error in aphakic and not aphakic persons with non-diseased eyes with myopia or hyperopia.	Indicated for daily wear for the correction of refractive error in aphakic and not aphakic persons with non-diseased eyes with myopia or hyperopia.
Actions	The contact lenses act as a refractive medium that focus light rays from near and distant objects on the retina	The contact lenses act as a refractive medium that focus light rays from near and distant objects on the retina	The contact lenses act as a refractive medium that focus light rays from near and distant objects on the retina	The contact lenses act as a refractive medium that focus light rays from near and distant objects on the retina
FDA Classification	Soft (hydrophilic) Contact Lens (21 CFR 886.5925)	Soft (hydrophilic) Contact Lens (21 CFR 886.5925)	Soft (hydrophilic) Contact Lens (21 CFR 886.5925)	Soft (hydrophilic) Contact Lens (21 CFR 886.5925)
FDA Group	FDA Group 4 (>50% H ₂ O, ionic polymer)	FDA Group 4 (>50% H ₂ O, ionic polymer)	FDA Group 4 (>50% H ₂ O, ionic polymer)	FDA Group 4 (>50% H ₂ O, ionic polymer)
Production Method	Fully molded	Fully molded	Fully molded	Fully molded
USAN name	methafilcon A	methafilcon A	vifilcon A	methafilcon A
Water Content (%)	55±2%	55±2%	55±2%	55±2%
Oxygen Permeability x 10 ⁻¹¹ (cm ² /sec)(mlO ₂)/(ml x mmHg @ 35°C)) (revised Fatt method)	20.4	20.7	16.0	19.7
Refractive Index (hydrated)	1.405	1.406	1.415	1.410
UV Blocker	Yes	Yes	Yes	Yes
Pad-Printed Tinting	Yes	No	No	Yes
Enhance Tinting	Yes	No	Yes	No

VII. PERFORMANCE DATA

The following performance data were provided in support of the substantial equivalence determination.

Non-clinical Testing

A series of preclinical testing was performed to demonstrate the safety and effectiveness of the **Sofclear Enhance, Colors, and Comfort (methafilcon A)** finished contact lenses. The results support the claim that the **Sofclear Enhance, Colors, and Comfort (methafilcon A) Daily Wear Contact Lenses** are substantially equivalent to the currently marketed predicate devices. A summary of the results from the preclinical studies is presented below.

Toxicology:

All non-clinical toxicology tests were conducted in accordance with the GLP regulation.

- In-Vitro Cytotoxicity: Cytotoxicity testing was performed in accordance with ISO 10993-5 with results indicating that the finished lenses and packaging materials are non-toxic.
- Systemic Toxicity: The finished lenses and packaging materials meet the requirements of the systemic injection test in accordance with ISO 10993-11 and are considered non-toxic.
- Acute Ocular Irritation: Acute ocular irritation test was performed in accordance with ISO 10993-10 and produced no ocular irritation for the finished lenses and packaging materials.

Shelf Life:

Testing was performed to evaluate the stability, sterility, and package integrity of the **Sofclear Enhance, Colors, and Comfort (methafilcon A)** finished contact lenses over the duration of the labeled expiration date. The data presented supports substantial equivalence of the contact lenses to the already marketed predicate devices.

Physicochemical & Mechanical Properties:

The following tests were completed to verify substantial equivalence: refractive index, water content, Dk, % transmission (visible & UV), tensile strength, modulus, % elongation to break, specific gravity and polymerization residuals. Results of physicochemical and mechanical property testing demonstrate consistent material properties between the **Sofclear Enhance, Colors, and Comfort (methafilcon A)** contact lenses and the predicate devices.

Clinical Testing

Clinical testing is not required. The clinical performance of soft (hydrophilic) contact lenses manufactured from methafilcon A materials has been demonstrated previously.

VIII. CONCLUSIONS

Validity of Scientific Data

Laboratories under Good Laboratory Practice regulations conducted toxicology, microbiology, and shelf-life stability studies following scientific protocols. The data were determined to be scientifically valid under 21 CFR 860.7.

Substantial Equivalence

Information presented in this Premarket Notification establishes that the **Sofclear Enhance, Colors, and Comfort (methafilcon A) Daily Wear Contact Lenses** are as safe and effective as the predicate device when used in accordance with the labeled directions for use and for the proposed indication.

Risks and Benefits

The risks of the subject device are the same as those normally attributed to the wearing of soft (hydrophilic) daily wear contact lenses. The benefits to the patient are the same as those for other soft (hydrophilic) daily wear contact lenses.