



Food and Drug Administration  
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April 8, 2016

EyeYon Medical  
% Mr. Bret Andre  
Principal Consultant  
EyeReg Consulting, Inc.  
6119 Canter Lane  
West Linn, OR 97068

Re: K153305

Trade/Device Name: EyeYon (hioxifilcon D) Soft (hydrophilic) Contact Lenses for Daily Wear, Hyper-CL (hioxifilcon D) Therapeutic Soft (hydrophilic) Contact Lenses for Daily Wear

Regulation Number: 21 CFR 886.5925

Regulation Name: Soft (Hydrophilic) Contact Lens

Regulatory Class: II

Product Code: LPL

Dated: February 25, 2016

Received: March 1, 2016

Dear Mr. 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. 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

510(k) Number (if known)

K153305

Device Name

EyeYon (hioxifilcon D) Soft (hydrophilic) Contact Lenses for Daily Wear (Sphere, Toric, Multifocal, Multifocal Toric)  
Hyper-CL™ (hioxifilcon D) Therapeutic Soft (hydrophilic) Contact Lenses for Daily Wear

Indications for Use (Describe)

The EyeYon (hioxifilcon D) Spherical soft contact lenses for daily wear are indicated for the correction of visual acuity 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 EyeYon (hioxifilcon D) Toric soft contact lenses for daily wear are indicated for the optical correction of refractive ametropia (myopia and hyperopia) in phakic or aphakic persons with non-diseased eyes with 4.00 diopters (D) or less of astigmatism.

The EyeYon (hioxifilcon D) Multifocal soft contact lenses for daily wear are indicated for the optical correction of refractive ametropia (myopia, hyperopia, and/or presbyopia) in phakic or aphakic persons with non-diseased eyes who may require a reading addition of +3.00 diopters (D) or less and who may have up to approximately 0.75 diopters of astigmatism.

The EyeYon (hioxifilcon D) Multifocal Toric soft contact lenses for daily wear are indicated for the optical correction of refractive ametropia (myopia, hyperopia, astigmatism and presbyopia) in phakic or aphakic persons with non-diseased eyes. The lenses may be worn by persons who have 4.00 diopters (D) or less of refractive and/or corneal astigmatism.

The Hyper-CL™ (hioxifilcon D) Therapeutic soft contact lenses for daily wear are indicated for the optical correction of refractive ametropia in phakic or aphakic persons with non-diseased eyes. The lenses may be prescribed for therapeutic use to promote corneal healing and relieve corneal pain by protecting the cornea during the treatment of acute or chronic pathologies, such as corneal edema, corneal erosions, entropion, bullous keratopathy, and corneal dystrophies as well as post-surgical conditions resulting from cataract extraction and corneal surgery.

Eyecare practitioners may prescribe the lenses for frequent/planned replacement wear, with cleaning, disinfection and scheduled replacement. When prescribed for frequent/planned replacement wear, the lens may be cleaned and disinfected using a chemical (not heat) lens care system.

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)

**PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.**

**FOR FDA USE ONLY**

Concurrence of Center for Devices and Radiological Health (CDRH) (Signature)

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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:                   K153305**

### **Applicant information:**

Date Prepared:	November 10 <sup>th</sup> , 2015
Name:	<b>EyeYon Medical</b>
Address:	Golda Meir 5 Nes Ziona Israel
Contact Person:	Malca Chen-Zion
Phone number:	+972.73.7803607
US Agent:	EyeReg Consulting, Inc. Bret Andre
Phone number:	(503) 333-2246
Fax number:	(503) 419-4475

### **Device Information:**

Device Classification:	Class II
Classification Number:	LPL
Classification Name:	Soft (hydrophilic) Contact Lens (21 CFR 886.5925)
Trade Name:	<b>EyeYon (hioxifilcon D) Soft (hydrophilic) Contact Lenses for Daily Wear (Sphere, Toric, Multifocal, Multifocal Toric)</b>  <b>Hyper-CL™ (hioxifilcon D) Therapeutic Soft (hydrophilic) Contact Lenses for Daily Wear</b>

**Equivalent Devices:**

The **EyeYon (hioxifilcon D) Soft (hydrophilic) Contact Lenses & Hyper-CL™ (hioxifilcon D) Therapeutic Soft (hydrophilic) Contact Lenses** are substantially equivalent to the following predicate device(s):

*Predicate device:*            **“CONTAFLEX 54 (hioxifilcon D)”**  
 Manufactured/distributed by Contamac Ltd.  
 510(k) number; **K150590**

**“CIBA VISION (lotrafilcon A)”**  
 Manufactured/distributed by CIBA VISION Corporation.  
 510(k) number; **K073459**

**EyeYon Medical & Hyper-CL™ (hioxifilcon D) Device Description:**

The **EyeYon (hioxifilcon D) Soft (hydrophilic) Contact Lenses & Hyper-CL™ (hioxifilcon D) Therapeutic Soft (hydrophilic) Contact Lenses for Daily Wear** are fabricated from hioxifilcon D, which in the dry (unhydrated) state may be machined and polished. The hydrophilic nature of this material allows the lens to become soft and pliable when immersed in an aqueous solution. The **EyeYon (hioxifilcon D) Soft (hydrophilic) Contact Lenses & Hyper-CL™ (hioxifilcon D) Therapeutic Soft (hydrophilic) Contact Lenses** are manufactured from CONTAFLEX 54 optical blanks, supplied by Contamac Ltd (cleared under K150590).

The non-ionic lens material, (hioxifilcon D) is a co-polymer of 2-Hydroxyethylmethacrylate (2-HEMA) and 2,3- Dihydroxypropyl Methacrylate (Glycerol Methacrylate), cross-linked with ethylene glycol dimethacrylate (EGDMA), plus an initiator. The co-polymer consists of 46% hioxifilcon D and 54% water by weight when immersed in normal buffered saline solution. The hioxifilcon D name has been adopted by the United States Adopted Names Council (USAN).

In the hydrated state, the lens conforms to the curvature of the eye covering the cornea and extending slightly beyond the limbus forming a colorless, transparent optical surface. The (hioxifilcon D) soft hydrophilic contact lens has a spherical back surface. The hydrophilic properties of the lens require that it be maintained in a fully hydrated state in a solution compatible with the eye. If the lens dries out, it will become hard and appear somewhat warped however, it will return to its proper configuration when completely rehydrated in the proper storage solution.

The **Hyper-CL™ (hioxifilcon D) Therapeutic Soft (hydrophilic) Contact Lens** design includes two (2) different base curves, and a peripheral groove including 4-16 fenestrations. When worn on the eye the Hyper-CL™ lens design creates a tear film reservoir between the corneal surface and the back surface of the contact lens. The fenestrations improve tear mixing efficiency.

The hydrophilic characteristics allow aqueous solutions to enter the lens and in its fully hydrated state the lens is approximately 54% water by weight. The physical properties of the **EyeYon & Hyper-CL™ (hioxifilcon D) Soft (hydrophilic) Contact Lenses** are:

<b>Refractive Index</b>	1.5193 (hydrated)
<b>Light Transmission</b>	greater than 96%
<b>Water Content</b>	54 % ± 2%
<b>Specific Gravity (wet)</b>	1.120
<b>Oxygen Permeability</b>	20.96 X 10 <sup>-11</sup> (cm <sup>2</sup> /sec) (ml O <sub>2</sub> /ml x mm Hg @ 35°C), (revised Fatt method).

The **EyeYon (hioxifilcon D) Soft (hydrophilic) Contact Lenses & Hyper-CL™ (hioxifilcon D) Therapeutic Soft (hydrophilic) Contact Lenses** are available in the following parameter ranges:

- **Diameter:** 10.0 mm to 17.0 mm
- **Base Curve:** 6.0 mm to 10.0 mm
- **Center Thickness:** varies (0.12 mm at +3.00 D)
- **Powers:** -20.00 D to +20.00 D (0.25 D steps)
  - **Toric:** up to -4.00 D (0.50 D steps)
  - **Multifocal:** up to +3.00 D

#### **Intended Use:**

The EyeYon (hioxifilcon D) Spherical soft contact lenses for daily wear are indicated for the correction of visual acuity 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 EyeYon (hioxifilcon D) Toric soft contact lenses for daily wear are indicated for the optical correction of refractive ametropia (myopia and hyperopia) in phakic or aphakic persons with non-diseased eyes with 4.00 diopters (D) or less of astigmatism.

The EyeYon (hioxifilcon D) Multifocal soft contact lenses for daily wear are indicated for the optical correction of refractive ametropia (myopia, hyperopia, and/or presbyopia) in phakic or aphakic persons with non-diseased eyes who may require a reading addition of +3.00 diopters (D) or less and who may have up to approximately 0.75 diopters of astigmatism.

The EyeYon (hioxifilcon D) Multifocal Toric soft contact lenses for daily wear are indicated for the optical correction of refractive ametropia (myopia, hyperopia, astigmatism and presbyopia) in phakic or aphakic persons with non-diseased eyes. The lenses may be worn by persons who have 4.00 diopters (D) or less of refractive and/or corneal astigmatism.

The Hyper-CL™ (hioxifilcon D) Therapeutic soft contact lenses for daily wear are indicated for the optical correction of refractive ametropia in phakic or aphakic persons with non-diseased eyes. The lenses may be prescribed for therapeutic use to promote corneal healing and relieve corneal pain by protecting the cornea during the treatment of acute or chronic pathologies, such as corneal edema, corneal erosions, entropion, bullous keratopathy, and corneal dystrophies as

well as post-surgical conditions resulting from cataract extraction and corneal surgery.

Eyecare practitioners may prescribe the lenses for frequent/planned replacement wear, with cleaning, disinfection and scheduled replacement. When prescribed for frequent/planned replacement wear, the lens may be cleaned and disinfected using a chemical (not heat) lens care system.

### **Summary of Non-Clinical Performance Data:**

The **EyeYon & Hyper-CL™ (hioxifilcon D) Soft (hydrophilic) Contact Lenses** are manufactured from CONTAFLEX 54 (hioxifilcon D) optical blanks, supplied by Contamac Ltd. The properties and safety profile for the CONTAFLEX 54 (hioxifilcon D) soft contact lens material may be referenced in K150590.

Additional non-clinical studies performed by EyeYon Medical include:

*Shelf Life Studies*—EyeYon Medical conducted studies (sterility, stability, package integrity) to establish expiration dating for the **EyeYon (hioxifilcon D) Soft (hydrophilic) Contact Lenses & Hyper-CL™ (hioxifilcon D) Therapeutic Soft (hydrophilic) Contact Lenses**.

*Manufacturing Verification (Bench Testing)*—manufacturing verification testing was conducted to demonstrate the ability of EyeYon Medical to manufacture lenses, on a repeatable basis, from (hioxifilcon D) optical blanks to a variety of prescribed parameters. All lenses were manufactured to established finished product specifications within the ANSI Z80.20 tolerance.

Non-clinical data presented in this submission support substantial equivalence of this **EyeYon & Hyper-CL™ (hioxifilcon D) Soft (hydrophilic) Contact Lens** to the already marketed CONTAFLEX 54 hioxifilcon D (K150590).

### **Substantial Equivalence:**

The **EyeYon (hioxifilcon D) Soft (hydrophilic) Contact Lenses & Hyper-CL™ (hioxifilcon D) Therapeutic Soft (hydrophilic) Contact Lenses** are substantially equivalent to the predicate device as depicted in the following table, and *do not raise* different questions of safety and effectiveness than the predicate device identified previously.

The following table depicts the pre-clinical characteristics of the **Hyper-CL™ (hioxifilcon D) Therapeutic Soft (hydrophilic) Contact Lens** materials, as well as the predicate devices:

### Substantial Equivalence Matrix

	<b>EyeYon Medical EyeYon &amp; Hyper-CL™ (Subject Device)</b>	<b>Contamac Ltd. CONTAFLEX 54 (Predicate Device)</b>	<b>CIBA VISION Corporation CIBA VISION Iotrafilcon A (Predicate Device)</b>
<b>Intended Use</b>	Same as predicate devices	Indicated for daily wear for the correction of visual acuity in aphakic and not aphakic persons with non-diseased eyes with myopia or hyperopia.	Indicated for therapeutic use to promote corneal healing and relieve corneal pain by protecting the cornea during the treatment of acute or chronic pathologies. Also may provide optical correction.
<b>Functionality</b>	Same as predicate devices	After machining from the optical blank, 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. May also be used as a bandage to protect and promote healing for the cornea.
<b>Classification Name</b>	Same as predicate devices	Soft (hydrophilic) Contact Lens (21 CFR 886.5925)	Soft (hydrophilic) Contact Lens (21 CFR 886.5925)
<b>Production Method</b>	Lathe cut	Lathe cut	Fully molded
<b>USAN name</b>	hioxifilcon D	hioxifilcon D	Lotrafilcon A
<b>Water Content (%)</b>	54±2%	54±2%	76±2%
<b>Oxygen Permeability</b>	$20.96 \times 10^{-11}$ (cm <sup>2</sup> /sec)(mlO <sub>2</sub> )/(ml x mmHg @ 35°C)) (revised Fatt method)	$20.96 \times 10^{-11}$ (cm <sup>2</sup> /sec)(mlO <sub>2</sub> )/(ml x mmHg @ 35°C)) (revised Fatt method)	$140 \times 10^{-11}$ (cm <sup>2</sup> /sec)(mlO <sub>2</sub> )/(ml x mmHg @ 35°C)) (revised Fatt method)
<b>FDA Group</b>	FDA Group 2 (>50% H <sub>2</sub> O, non-ionic polymer)	FDA Group 2 (>50% H <sub>2</sub> O, non-ionic polymer)	FDA Group 1 (<50% H <sub>2</sub> O, non-ionic polymer)
<b>Specific Gravity</b>	1.12 (hydrated)	1.12 (hydrated)	-