



Food and Drug Administration  
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July 10, 2015

Contamac Ltd.  
% Mr. Bret Andre  
Official Correspondent  
EyeReg Consulting, Inc.  
474 NE 61<sup>st</sup> PL  
Hillsboro, Oregon 97124

Re: K150590

Trade/Device Name: Contaflex 54 (hioxifilcon D) Spherical Soft Contact Lens  
for Daily Wear

Contaflex 49 (hioxifilcon B) Spherical Soft Contact Lens  
for Daily Wear

Regulation Number: 21 CFR 886.5925

Regulation Name: Soft (Hydrophilic) Contact Lens

Regulatory Class: Class II

Product Code: LPL

Dated: June 4, 2015

Received: June 8, 2015

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,

**Kesia Y. Alexander -A**

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)  
K150590

Device Name

CONTAFLEX 54 (hioxifilcon D) Spherical Soft (hydrophilic) Contact Lens for Daily Wear (clear and tinted, lathe-cut);  
CONTAFLEX 49 (hioxifilcon B) Spherical Soft (hydrophilic) Contact Lens for Daily Wear (clear and tinted, lathe-cut)

Indications for Use (Describe)

The CONTAFLEX 54 (hioxifilcon D) Spherical Soft (hydrophilic) Contact Lenses for daily wear are indicated for the correction of refractive ametropia (myopia and hyperopia) in aphakic and not aphakic persons with non-diseased eyes. The lens may be worn by persons who exhibit refractive astigmatism of .75 diopters or less where the astigmatism does not interfere with visual acuity. The lens may be disinfected using a chemical disinfecting system.

The CONTAFLEX 49 (hioxifilcon B) Spherical Soft (hydrophilic) Contact Lenses for daily wear are indicated for the correction of refractive ametropia (myopia and hyperopia) in aphakic and not aphakic persons with non-diseased eyes. The lens may be worn by persons who exhibit refractive astigmatism of .75 diopters or less where the astigmatism does not interfere with visual acuity. The lens may be disinfected using a chemical disinfecting system.

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)

### 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:**                    **K150590**

### **Applicant information:**

|                 |  |
|-----------------|--|
| Date Prepared:  | March 3 <sup>rd</sup> , 2015   |
| Name:           | <b>CONTAMAC Ltd.</b>   |
| Address         | Bearwalden Business Park<br>Saffron Walden<br>Essex England CB11 4JX |
| Contact Person: | Robert McGregor  |
| Phone number:   | 44-1799 542 000  |
| US Agent:       | EyeReg Consulting, Inc.<br>Bret Andre                                |
| Phone number    | (503) 372-5226   |
| 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>CONTAFLEX 54 (hioxifilcon D) Spherical Soft (hydrophilic) Contact Lens for Daily Wear (clear and tinted, lathe-cut)</b><br><br><b>CONTAFLEX 49 (hioxifilcon B) Spherical Soft (hydrophilic) Contact Lens for Daily Wear (clear and tinted, lathe-cut)</b> |

**Equivalent Devices:**

The CONTAFLEX 54 (hioxifilcon D) & CONTAFLEX 49 (hioxifilcon B) Spherical Soft (hydrophilic) Contact Lenses are substantially equivalent to the following predicate device(s):

*Predicate device:*            **“BENZ-G 4X hioxifilcon D”**  
 Manufactured/distributed by Benz Research and Development.  
 510(k) number; **K062854**

**“BENZ-G 3X hioxifilcon B”**  
 Manufactured/distributed by Benz Research and Development.  
 510(k) number; **K964528**

**CONTAFLEX 54 (hioxifilcon D) Device Description:**

The CONTAFLEX 54 Spherical Soft (hydrophilic) Contact Lenses 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 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 lens is available in clear and with a blue visibility-handling tint, [phthalocyaninato (2-)] copper. 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 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 lens are:

|                                    |  |
|------------------------------------|--|
| <b>Refractive Index</b>            | 1.5193 (hydrated)  |
| <b>Light Transmission (clear)</b>  | greater than 96%   |
| <b>Light Transmission (tinted)</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),<br>(revised Fatt method). |

**CONTAFLEX 49 (hioxifilcon B) Device Description:**

The CONTAFLEX 49 Spherical Soft (hydrophilic) Contact Lenses are fabricated from hioxifilcon B, 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 non-ionic lens material, (hioxifilcon B) 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 51% hioxifilcon B and 49% water by weight when immersed in normal buffered saline solution. The lens is available in clear and with a blue visibility-handling tint, [phthalocyaninato (2-)] copper. The hioxifilcon B 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 B) 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 hydrophilic characteristics allow aqueous solutions to enter the lens and in its fully hydrated state the lens is approximately 49% water by weight. The physical properties of the lens are:

|                                    |  |
|------------------------------------|--|
| <b>Refractive Index</b>            | 1.5164 (hydrated)  |
| <b>Light Transmission (clear)</b>  | greater than 96%   |
| <b>Light Transmission (tinted)</b> | greater than 96%   |
| <b>Water Content</b>               | 49% ± 2%   |
| <b>Specific Gravity (wet)</b>      | 1.140  |
| <b>Oxygen Permeability</b>         | 16.09 X 10 <sup>-11</sup> (cm <sup>2</sup> /sec) (ml O <sub>2</sub> /ml x mm Hg @ 35°C),<br>(revised Fatt method). |

**Intended Use:**

The **CONTAFLEX 54 (hioxifilcon D) Spherical Soft** (hydrophilic) Contact Lenses for daily wear are indicated for the correction of refractive ametropia (myopia and hyperopia) in aphakic and not aphakic persons with non-diseased eyes. The lens may be worn by persons who exhibit refractive astigmatism of .75 diopters or less where the astigmatism does not interfere with visual acuity. The lens may be disinfected using a chemical disinfecting system.

The **CONTAFLEX 49 (hioxifilcon B) Spherical Soft** (hydrophilic) Contact Lenses for daily wear are indicated for the correction of refractive ametropia (myopia and hyperopia) in aphakic and not aphakic persons with non-diseased eyes. The lens may be worn by persons who exhibit refractive astigmatism of .75 diopters or less where the astigmatism does not interfere with visual acuity. The lens may be disinfected using a chemical disinfecting system.

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.

**Description of Safety:**

A series of preclinical testing were performed to demonstrate the safety and effectiveness of the CONTAFLEX 54 & CONTAFLEX 49 Soft (hydrophilic) Contact Lens materials. The results of all testing demonstrated that the safety and effectiveness of the CONTAFLEX 54 & CONTAFLEX 49 Soft (hydrophilic) Contact Lenses are equivalent to the currently marketed Benz hioxifilcon D (K062854) & hioxifilcon B (K964528) contact lens materials. A summary of these results from the preclinical studies is presented below.

Toxicology:

In-Vitro Cytotoxicity: ISO 10993-5 was conducted in accordance with standards on test article. The test article meets the requirements of the Agarose Overlay Method.

Systemic Toxicity: The lens material meets the requirements of the systemic injection test and is considered non-toxic.

Acute Ocular Irritation: Acute ocular irritation test was performed and produced no ocular irritation.

Shelf Life

The data presented supports substantial equivalence of this CONTAFLEX 54 & CONTAFLEX 49 Soft (hydrophilic) Contact Lens material to the already marketed Benz hioxifilcon D (K062854) & hioxifilcon B (K964528).

**Substantial Equivalence:**

The CONTAFLEX 54 & CONTAFLEX 49 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 CONTAFLEX 54 & CONTAFLEX 49 materials, as well as the predicate devices.

### Substantial Equivalence Matrix

|                            | <b>Contamac ltd.<br/>CONTAFLEX 54<br/>(Subject Device)</b>   | <b>Contamac ltd.<br/>CONTAFLEX 49<br/>(Subject Device)</b>   | <b>Benz Research and<br/>Development<br/>BENZ-G 4X<br/>(Predicate Device)</b>  | <b>Benz Research and<br/>Development<br/>BENZ-G 3X<br/>(Predicate Device)</b>  |
|----------------------------|--|--|--|--|
| <b>Intended Use</b>        | 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 daily wear for the correction of visual acuity in aphakic and not aphakic persons with non-diseased eyes with myopia or hyperopia.         | 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 daily wear for the correction of visual acuity in aphakic and not aphakic persons with non-diseased eyes with myopia or hyperopia.         |
| <b>Functionality</b>       | 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. | 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. | 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. | 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. |
| <b>Indications</b>         | Soft (hydrophilic) Contact Lens (21 CFR 886.5925)  |
| <b>Production Method</b>   | Lathe cut  | Lathe cut  | Lathe cut  | Lathe cut  |
| <b>USAN name</b>           | hioxifilcon D  | hioxifilcon B  | hioxifilcon D  | hioxifilcon B  |
| <b>Water Content (%)</b>   | 54±2%  | 49±2%  | 54±2%  | 49±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)  | $16.09 \times 10^{-11}$ (cm <sup>2</sup> /sec)(mlO <sub>2</sub> )/(ml x mmHg @ 35°C)) (revised Fatt method)  | $20.09 \times 10^{-11}$ (cm <sup>2</sup> /sec)(mlO <sub>2</sub> )/(ml x mmHg @ 35°C)) (revised Fatt method)  | $15.71 \times 10^{-11}$ (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 1 (<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)  | 1.14 (hydrated)  | 1.10 (hydrated)  | 1.15 (hydrated)  |