



Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Center - WO66-G609  
Silver Spring, MD 20993-0002

February 11, 2016

Bausch & Lomb, Inc.  
Ms. Barbara Klube-Falso  
Manager, Regulatory Affairs  
1400 North Goodman Street  
Rochester, NY 14609

Re: K151918

Trade/Device Name: Biotrue Oneday with NaturMoist;  
Biotrue Oneday for Presbyopia with NaturMoist;  
Biotrue Oneday for Astigmatism with NaturMoist  
Regulation Number: 21 CFR 886.5925  
Regulation Name: Soft (Hydrophilic) Contact Lens  
Regulatory Class: Class II  
Product Code: LPL, MVN  
Dated: January 4, 2016  
Received: January 5, 2016

Dear Ms. Klube-Falso:

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 Alexander

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)  
K151918

Device Name  
Biotrue ONEday Contact Lenses with NaturMoist

### Indications for Use (Describe)

#### Spherical:

The Bausch + Lomb Biotrue® ONEday (nesofilcon A) Contact Lens with NaturMoist is indicated for the daily wear correction of refractive ametropia (myopia, hyperopia, astigmatism) in aphakic and/or non-aphakic persons with non-diseased eyes that exhibit refractive astigmatism up to 2.00 diopters or less, that does not interfere with visual acuity. The lens is to be prescribed in spherical powers ranging from +20.00D to -20.00D.

#### Multifocal:

The Bausch + Lomb Biotrue® ONEday for Presbyopia (nesofilcon A) Soft (Hydrophilic) Contact Lens with NaturMoist is indicated for daily wear for the correction of refractive ametropia (myopia, hyperopia, and astigmatism) and presbyopia in aphakic and/or not-aphakic persons with non-diseased eyes, exhibiting astigmatism of 2.00 diopters or less, that does not interfere with visual acuity. The lens provides a power range of +20.00 to -20.00 diopters with add power ranging from +0.75D to +5.00D.

#### Toric:

The Bausch + Lomb Biotrue ONEday for Astigmatism (nesofilcon A) Soft (hydrophilic) Contact Lens with NaturMoist is indicated for daily wear for the correction of refractive ametropia (myopia, hyperopia and astigmatism) in aphakic and/or not-aphakic persons with non-diseased eyes, exhibiting astigmatism of up to 5.00 diopters, that does not interfere with visual acuity. The lens provides a power range of +20.00 to -20.00 diopters for daily wear.

The lens is to be prescribed for single-use disposable wear, and 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

#### **\*DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.\***

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services  
Food and Drug Administration  
Office of Chief Information Officer  
Paperwork Reduction Act (PRA) Staff  
PRAStaff@fda.hhs.gov

*"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."*

**510(k) Summary**     K151918

**Date Prepared**     July 10, 2015

**Applicant**     Bausch & Lomb Incorporated  
1400 North Goodman Street, Rochester, New York 14609  
585.338.8503

**Contact**     Barbara Klube-Falso

**Trade names**     Biotrue ONEday (nesofilcon A) Soft (Hydrophilic) Contact Lens with NaturMoist  
  
Biotrue ONEday for Presbyopia (nesofilcon A) Soft (Hydrophilic) Contact Lens with NaturMoist  
  
Biotrue ONEday for Astigmatism (nesofilcon A) Soft (Hydrophilic) Contact Lens with NaturMoist

**Common name**     soft contact lenses (hydrophilic)

**Classification**     Class II (21 CFR 886.5925 (b) (1))

**Predicate Devices**     Biotrue ONEday (nesofilcon A) Soft (Hydrophilic) Contact Lenses cleared under K113703,  
  
Biotrue ONEday for Presbyopia (nesofilcon A) Soft (Hydrophilic) Contact Lenses cleared under K132715, and  
  
Biotrue ONEday for Astigmatism (nesofilcon A) Soft (hydrophilic) Contact Lenses cleared under K143632.

**Device Description:**

The Biotrue ONEday Contact Lens with NaturMoist is a soft hydrophilic contact lens. The lenses are made from the nesofilcon A material, a hydrophilic copolymer of 2-hydroxyethyl methacrylate and N-vinyl pyrrolidone, and is 78% water by weight when immersed in a sterile borate buffered saline solution with poloxamine and sodium hyaluronate. A UV-absorbing monomer is used to block UV radiation. The transmittance characteristics are less than 5% in the UVB range of 280nm to 315nm and less than 50% in the UVA range of 316nm to 380nm. This lens is tinted blue with Reactive Blue Dye 246. The color additive conforms to 21 CFR Part 73.3106.

The physical / optical properties of the lens are:

Specific Gravity:     1.039

Refractive Index:     1.374

Light Transmittance: 99%

Water Content:     78%

Oxygen Permeability:  $42 \times 10^{-11} [\text{cm}^3 \text{O}_2(\text{STP}) \times \text{cm}] / (\text{sec} \times \text{cm}^2 \times \text{mmHg}) @ 35^\circ \text{C}$   
(polarographic method)

The lenses will be manufactured in the following parameter ranges:

Diameter:	13.5mm to 15.5mm
Center Thickness:	0.05mm to 0.75mm (varies with power)
Base Curve:	7.8mm to 9.5mm
Power Range:	+20.00D to -20.00D
Add Power:	+0.75D to +5.00D
Cylinder Powers:	-0.75D to -5.00D
Cylinder Axis:	0 <sup>0</sup> to 180 <sup>0</sup>

### **Indications for Use:**

#### **Biotrue ONEday Contact Lenses with NaturMoist**

##### **Spherical:**

The Bausch + Lomb Biotrue<sup>®</sup> ONEday (nesofilcon A) Soft (Hydrophilic) Contact Lens with NaturMoist is indicated for the daily wear correction of refractive ametropia (myopia, hyperopia, astigmatism) in aphakic and/or non-aphakic persons with non-diseased eyes that exhibit refractive astigmatism up to 2.00 diopters or less, that does not interfere with visual acuity. The lens is to be prescribed in spherical powers ranging from +20.00D to -20.00D.

##### **Multifocal:**

The Bausch + Lomb Biotrue<sup>®</sup> ONEday for Presbyopia (nesofilcon A) Soft (Hydrophilic) Contact Lens with NaturMoist is indicated for daily wear for the correction of refractive ametropia (myopia, hyperopia, and astigmatism) and presbyopia in aphakic and/or not-aphakic persons with non-diseased eyes, exhibiting astigmatism of 2.00 diopters or less, that does not interfere with visual acuity. The lens provides a power range of +20.00 to -20.00 diopters with add power ranging from +0.75D to +5.00D.

##### **Toric:**

The Bausch + Lomb Biotrue ONEday for Astigmatism (nesofilcon A) Soft (hydrophilic) Contact Lens with NaturMoist is indicated for daily wear for the correction of refractive ametropia (myopia, hyperopia and astigmatism) in aphakic and/or not-aphakic persons with non-diseased eyes, exhibiting astigmatism of up to 5.00 diopters, that does not interfere with visual acuity. The lens provides a power range of +20.00 to -20.00 diopters for daily wear.

The lens is to be prescribed for single-use disposable wear, and is to be discarded after each removal.

**Technological Characteristics**

<b>Property</b>	<b>Biotrue ONEday SVS (predicate)</b>	<b>Biotrue ONEday Multi-Focal (predicate)</b>	<b>Biotrue ONEday Toric (predicate)</b>	<b>Biotrue ONEday Contact Lenses with NaturMoist (Subject Device)</b>
Functionality	The contact lens acts as a refractive medium that focus light rays from near and distant objects on the retina.	The contact lens acts as a refractive medium that focus light rays from near and distant objects on the retina.	The contact lens acts as a refractive medium that focus light rays from near and distant objects on the retina.	Same as predicate
Modality	Daily wear contact lens	Daily wear contact lens	Daily wear contact lens	Same as predicate
Manufacturing Method	Cast Mold	Cast Mold	Cast Mold	Same as predicate
Material Group	Group II (high water, no ionic polymers)	Group II (high water, no ionic polymers)	Group II (high water, no ionic polymers)	Same as predicate
USAN Name	Nesofilcon A	Nesofilcon A	Nesofilcon A	Same as predicate
Water Content	78%	78%	78%	Same as predicate
UV Blocker	yes	yes	yes	Same as predicate
Sterilization	Air over steam	Air over steam	Air over steam	Same as predicate
Physical/optical properties	Specific Gravity: 1.039 Refractive index: 1.374 Surface Character: Hydrophilic	Specific Gravity: 1.039 Refractive index: 1.374 Surface Character: Hydrophilic	Specific Gravity: 1.039 Refractive index: 1.374 Surface Character: Hydrophilic	Same as predicate
Oxygen Permeability	$42 \times 10^{-11}^*$	$42 \times 10^{-11}^*$	$42 \times 10^{-11}^*$	Same as predicate
Light Transmittance	99%	99%	99%	Same as predicate
Color Additive	Reactive Blue Dye 246	Reactive Blue Dye 246	Reactive Blue Dye 246	Same as predicate
Lens Design	Spherical	Multi-Focal	Toric	Same as predicates
Packaging	Polypropylene blister with plastic coated aluminum foil blister	Polypropylene blister with plastic coated aluminum foil blister	Polypropylene blister with plastic coated aluminum foil blister	Same as predicate

Difference				
Packaging Solution	Borate Buffered Saline with poloxamine and sodium hyaluronate			

\* $[\text{cm}^3\text{O}_2(\text{STP}) \times \text{cm}]/(\text{sec} \times \text{cm}^2 \times \text{mmHg})@35^\circ\text{C}$  (polarographic method)

**Summary of Non-Clinical Performance Data**

**Non-Clinical Tests:** Testing conducted followed FDA guidance, FDA Premarket Notification 510(k) Guidance Document for Daily Wear Contact Lenses, May 1994. The testing performed demonstrated that the devices continue to function in a safe and effective manner. Performance testing included conformance to predetermined specifications, functional test results verify that the device performs as expected and is equivalent to the predicate without creating additional risk to the user.

**Clinical Tests:** The technological characteristics, formulation, manufacturing and sterilization processes are the same as the predicate device, therefore, no clinical studies were required to demonstrate the safety or effectiveness of the subject device.

**Substantial Equivalence:**

The Biotrue ONEday Contact Lenses with NaturMoist are substantially equivalent to the predicate devices as they have the same functional and scientific technology, lens characteristics and the intended use is identical to that of the predicate device.