



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

February 13, 2015

Bausch & Lomb Incorporated  
Ms. Jessica M. Burger  
Specialist, Regulatory Affairs  
1400 North Goodman Street  
Rochester, New York 14609

Re: K143632  
Trade/Device Name: Bausch + Lomb Biotrue Oneday For Astigmatism (nesofilcon A)  
Soft (hydrophilic) Contact Lens  
Regulation Number: 21 CFR 886.5925  
Regulation Name: Soft (Hydrophilic) Contact Lens  
Regulatory Class: Class II  
Product Code: LPL, MVN  
Dated: December 18, 2014  
Received: December 22, 2014

Dear Ms. Burger:

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 -S**

for Malvina B. Eydelman, MD  
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)

K143632

Device Name

Bausch + Lomb Biotrue ONEday for Astigmatism (nesofilcon A) Soft (hydrophilic) Contact Lens

Indications for Use (Describe)

The Bausch + Lomb Biotrue ONEday for Astigmatism (nesofilcon A) Soft (hydrophilic) Contact Lens is indicated for daily wear for the correction of refractive ametropia (myopia, hyperopia and astigmatism) in aphakic and/or not-aphakic persons with nondiseased 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  
[PRASStaff@fda.hhs.gov](mailto:PRASStaff@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."*

<b>Bausch + Lomb</b> <b>Traditional 510(k) Premarket Notification</b> <b>Bausch + Lomb Biotrue ONEday for</b> <b>Astigmatism (nesofilcon A) Contact Lens</b>	<b>510(K) SUMMARY</b>
---	-----------------------

## 510(k) Summary

### Submitter Information:

Date Prepared: December 18, 2014  
Name: Bausch & Lomb Incorporated  
Address: 1400 North Goodman Street  
Rochester, NY 14609  
Contact Person: Jessica M. Burger  
Specialist, Regulatory Affairs  
Phone Number: (585) 338-5665  
(585) 338-0702 (fax)  
Email: Jessica.Burger@bausch.com

### Device Information:

Trade Names: Bausch + Lomb Biotrue ONEday for Astigmatism (nesofilcon A)  
Soft (hydrophilic) Contact Lens  
Common Name: Soft daily disposable contact lens  
Classification Name: Soft (hydrophilic) contact lens (21 CFR 886.5925)  
Device Classification: Class II  
Product Code: LPL, MVN

### Predicate Devices:

- Bausch + Lomb nesofilcon A Contact Lens (K113703)
- Bausch + Lomb (samfilcon A) Contact Lens for Astigmatism (K131208)

### Device Description:

The Bausch + Lomb Biotrue ONEday for Astigmatism (nesofilcon A) Soft (hydrophilic) Contact Lens is made from nesofilcon A material, a hydrophilic copolymer of 2-hydroxyethyl methacrylate and N-vinyl pyrrolidone. The lens is 78% water by weight when immersed in a sterile borate buffered saline with poloxamine solution. A UV-absorbing monomer is used to block UV radiation. The transmittance characteristics are

<b>Bausch + Lomb</b> <b>Traditional 510(k) Premarket Notification</b> <b>Bausch + Lomb Biotrue ONEday for</b> <b>Astigmatism (nesofilcon A) Contact Lens</b>	<b>510(K) SUMMARY</b>
---	-----------------------

less than 5% in the UVB range of 280nm to 315nm and less than 50% in the UVA range of 316nm to 380nm. The lenses are tinted blue for visibility with Reactive Blue Dye 246. The color additive conforms to 21 CFR Part 73.3106.

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

The physical properties of the lens are:

Refractive index	1.374
Light transmission	99%
Water Content	78%
Specific Gravity	1.039
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 lens will be manufactured in the following parameter ranges:

Diameter	13.5mm to 15.0mm
Center Thickness	0.05mm to 0.75mm (varies with power)
Base Curve	7.8mm to 9.5mm
Power Range	+20.00D to -20.00D
Cylinder Powers	-0.75D to -5.00D
Cylinder Axis	0° to 180°

The lens is packaged in disposable blister packages containing borate buffered saline solution with poloxamine and provided sterile. Blister packages are labeled with the lot number, expiration date and applicable lens parameters.

#### **Indications for Use:**

The Bausch + Lomb Biotrue ONEday for Astigmatism (nesofilcon A) Soft (hydrophilic) Contact Lens 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.

<b>Bausch + Lomb</b> <b>Traditional 510(k) Premarket Notification</b> <b>Bausch + Lomb Biotrue ONEday for</b> <b>Astigmatism (nesofilcon A) Contact Lens</b>	<b>510(K) SUMMARY</b>
---	-----------------------

**Technological Characteristics (comparison to Predicate Device)**

<b>Property</b>	<b>Predicate Device</b> Bausch + Lomb nesofilcon A Contact Lens	<b>New Device</b> Bausch + Lomb Biotrue ONEday for Astigmatism (nesofilcon A) Contact Lens
Functionality	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	Same as predicate
Manufacturing Method	Cast Molded	Same as predicate
Material Group	Group II (high water, no ionic polymers)	Same as predicate
USAN Name	nesofilcon A	Same as predicate
Water Content	78%	Same as predicate
UV Blocker	Yes	Same as predicate
Sterilization	Air over steam	Same as predicate
Packaging	Polypropylene blister with plastic coated aluminum foil blister	Same as predicate
Packaging solution	Borate buffered saline with poloxamine	Same as predicate

<b>Bausch + Lomb</b> <b>Traditional 510(k) Premarket Notification</b> <b>Bausch + Lomb Biotrue ONEday for</b> <b>Astigmatism (nesofilcon A) Contact Lens</b>	<b>510(K) SUMMARY</b>
---	-----------------------

The lens design and indications for use of the proposed device are identical to the selected predicate device as identified in the table below.

<b>Property</b>	<b>Predicate Device</b>	<b>New Device</b>
	Bausch + Lomb (samfilcon A) Contact Lens for Astigmatism	Bausch + Lomb Biotrue ONEday for Astigmatism (nesofilcon A) Contact Lens
Lens Design	Toric	Same as predicate
Indication for Use	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 5.0 diopters, that does not interfere with visual acuity.	Same as predicate

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

A series of *in vitro* and *in vivo* preclinical toxicology and biocompatibility testing was performed to assess the safety and effectiveness of the contact lens material, nesofilcon A. Testing was performed in accordance with the FDA guidance *Premarket Notification (510(k)) Guidance Document For Daily Wear Contact Lenses*, May 1994 and GLP regulation 21 CFR part 58 and included the following:

- Leachables
- Ocular Irritation – Lens device, Packaging, Lens Mold
- Sensitization
- Systemic Toxicity – Lens device, Packaging, Lens Mold

Performance testing included conformance to predetermined specifications and functional testing to verify that the device performs as expected without creating additional risk to the user.

Stability testing, both real-time and accelerated aging, was performed on the nesofilcon A Contact Lens and demonstrates that the product is stable for four years.

The testing performed on the predicate device, Bausch + Lomb nesofilcon A Contact Lens, demonstrated that the device functions in a safe and effective manner. The subject device is of the identical lens material, manufacturing process, sterilization process, and packaging as the predicate device, and the finished lens parameters fall within the ranges previously cleared for the predicate device and therefore the previous testing is fully applicable.

<b>Bausch + Lomb</b> <b>Traditional 510(k) Premarket Notification</b> <b>Bausch + Lomb Biotrue ONEday for</b> <b>Astigmatism (nesofilcon A) Contact Lens</b>	<b>510(K) SUMMARY</b>
---	-----------------------

### **Summary of Clinical Performance Data**

Clinical performance data to confirm safety and effectiveness of the nesofilcon A lens material in the daily disposable modality was obtained via a clinical study of the Bausch + Lomb nesofilcon A Contact Lens. Due to the similarities between the Bausch + Lomb Biotrue ONEday for Astigmatism (nesofilcon A) Contact Lens (subject device) and the Bausch + Lomb nesofilcon A Contact Lens (predicate device), the clinical study performed on the predicate device is applicable to the subject device and no additional clinical study was performed.

### **Substantial Equivalence Conclusion:**

The information submitted in this premarket notification supports the determination that the Bausch + Lomb Biotrue ONEday for Astigmatism (nesofilcon A) Contact Lens is substantially equivalent in principles of operation, technology, materials and indications for use to the predicate devices listed above.