DEC 2 0 2013

510(k) Summary

Submitter Information:

Date Prepared:	December 20, 2013
Name:	Bausch & Lomb Incorporated
Address:	1400 North Goodman Street Rochester, NY 14609
Contact Person:	Jennifer Knicley Sr. Manager, Regulatory Affairs
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Device Information:

Trade Names:	Bausch + Lomb Biotrue® ONEday for Presbyopia (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:	MVN, LPL

Predicate Devices:

- Bausch + Lomb nesofilcon A contact lens (K113703)
- BAUSCH & LOMB PureVision® Multi-Focal (balafilcon A) Visibility Tinted Contact Lens (K050948)

Device Description:

The Bausch + Lomb Biotrue® ONEday for Presbyopia (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

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 x 10^{-11}[cm^3O_2(STP) x cm]/(sec x cm^2 x mmHg)@35°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
Add Power	+0.75D to +5.00D

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 Presbyopia (nesofilcon A) Soft (Hydrophilic) Contact Lens 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.

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

Technological Characteristics (comparison to Predicate Device)

Property	**Predicate Device** Bausch + Lomb nesofilcon A contact lens	**New Device** Bausch + Lomb Biotrue® ONEday for Presbyopia (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 aluminium foil blister	Same as predicate
Packaging solution	Borate buffered saline with poloxamine	Same as predicate

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

Property	Predicate Device BAUSCH & LOMB PureVision® Multi-Focal (balafilcon A) Visibility Tinted Contact Lens	New Device Bausch + Lomb Biotrue® ONEday for Presbyopia (nesofilcon A) Contact Lens
Lens Design	Multifocal	Same as predicate
Indication for Use	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	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 titled *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.

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 Presbyopia (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 Presbyopia (nesofilcon A) Contact Lens is substantially equivalent in principles of operation, technology, materials and indications for use to the predicate devices listed above.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

December 20, 2013

Bausch + Lomb, Incorporated
% Ms. Jennifer S. Knicley
Senior Manager, Regulatory Affairs
1400 North Goodman Street
Rochester, NY 14609

Re: K132715
Trade/Device Name: Bausch + Lomb Biotrue ONEday for Presbyopia (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: November 22, 2013
Received: November 25, 2013

Dear Ms. Knicley:

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 Small Manufacturers, International and Consumer Assistance 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" (21CFR 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 Small Manufacturers, International and Consumer Assistance 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, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Bausch + Lomb Traditional 510(k) Premarket Notification Bausch + Lomb Biotrue ONEday for Presbyopia (nesofilcon A) Contact Lens	INDICATIONS FOR USE

Indications for Use Statement

510(k) Number (if known): K132715

Device Name: Bausch + Lomb Biotrue® ONEday for Presbyopia (nesofilcon A) Soft (Hydrophilic) Contact Lens

Indications for Use:
The Bausch + Lomb Biotrue® ONEday for Presbyopia (nesofilcon A) Soft (Hydrophilic) Contact Lens 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.

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

Prescription Use ___✓___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of Center for Devices and Radiological Health (CDRH)

J Angelo Green -S
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(Division Sign-Off)
Division of Ophthalmic and Ear, Nose and Throat Devices

510(k) Number: K132715