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

May 2, 2016

Alcon Laboratories, Inc.
Ms. Alicia Plesnarski
Director, Global Regulatory Affairs
6201 South Freeway
Fort Worth, Texas 76134-2099

Re: K160609
Trade/Device Name: Air Optix Plus Hydraglyde, Air Optix Plus Hydraglyde For Astigmatism, Air Optix Plus Hydraglyde Multifocal, Air Optix Plus Hydraglyde Multifocal Toric
Regulation Number: 21 CFR 886.5925
Regulation Name: Soft (Hydrophilic) Contact Lens
Regulatory Class: Class II
Product Code: LPL, MVN
Dated: February 29, 2016
Received: March 3, 2016

Dear Ms. Plesnarski:

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 and Part 809); 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 and Part 809), 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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K160609

Device Name

AIR OPTIX plus HydraGlyde (lotrafilcon B) soft contact lenses

Indications for Use *(Describe)*

Lotrafilcon B spherical soft contact lenses are indicated for the optical correction of refractive ametropia (myopia and hyperopia) in phakic or aphakic persons with non-diseased eyes and up to approximately 1.50 diopters of astigmatism that does not interfere with visual acuity.

Lotrafilcon B toric soft contact lenses are indicated for the optical correction of refractive ametropia (myopia and hyperopia) in phakic or aphakic persons with non-diseased eyes and up to 6.00 diopters (D) or less of astigmatism.

Lotrafilcon B multifocal soft contact lenses are indicated for the optical correction of presbyopia with or without refractive ametropia (myopia and hyperopia) 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 1.50 diopters of astigmatism.

Lotrafilcon B multifocal toric soft contact lenses are indicated for the optical correction of refractive ametropia (myopia and hyperopia) and presbyopia in phakic or aphakic persons with non-diseased eyes and up to 6.00 diopters (D) or less of refractive and/or corneal astigmatism.

Eye care professionals may prescribe the lenses for daily disposable wear (lenses are discarded upon removal from the eye) or daily wear with removal for cleaning and disinfection (chemical, not heat) prior to reinsertion and frequent replacement, as recommended by the eye care professional.

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

This summary document is being prepared in accordance with section 21 CFR 807.92.

The submitter of the 510(k) is:

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Date Summary Prepared: 12 April 2016

Device Subject to this 510(k):

Trade Name:	AIR OPTIX® plus HydraGlyde®
Common Name:	(lotrafilcon B) Soft Contact Lens
Classification Name:	Soft (hydrophilic) Contact Lens [21 CFR 886.5925 (b) (1)]
Product code:	LPL; MVN

Predicate Device(s)

The predicate device is the Alcon® AIR OPTIX® AQUA (lotrafilcon B) contact lens packaged in phosphate buffered saline (PBS) +1% Copolymer 845. Lotrafilcon B contact lenses are a Group V silicone hydrogel according to ISO 18369-1:2006/Amd. 1:2009. The predicate device (in PBS saline or PBS +1% Copolymer saline) has FDA Premarket Notification 510(k) clearance for daily wear (K033919, March 12, 2004; K073459, 28-Feb-2008).

Device Description

The lens material is 33% water and 67% lotrafilcon B, a fluoro-silicone containing hydrogel which is surface treated. Contact lenses contain the color additive phthalocyanine blue, a light blue handling tint, which helps make them easier to see when handling.

Lotrafilcon B lens designs include spherical, toric, multifocal and multifocal toric lenses in the following parameter ranges:

- Diameter Range: 13.0 to 15.0 mm
- Base Curve Range: 8.0 to 9.2 mm
- Power Range: -20.00D to +20.00D
- Center Thickness: varies with design and power (Example: 0.08 mm for -3.00D spherical)

Lenses have the following properties:

- Refractive index: 1.42 (hydrated)
- Light transmittance: > 94 %
- Water content : 33% by weight in normal saline
- Oxygen permeability 110×10^{-11} $[(cm^2/sec)(ml\ O_2/ml \bullet mmHg)]$ measured at 35°C (intrinsic Dk-Coulometric method)

Lotrafilcon B contact lenses are supplied sterile in sealed blister packs containing isotonic phosphate buffered saline solution (PBS) with or without additives [1% Copolymer 845, or 1% Copolymer 845 and 0.04% (400 ppm) polyoxyethylene-polyoxybutylene copolymer ($EO_{45}BO_{10}$)]. The compatibility and package integrity of the blister pack packaging system have been demonstrated and successfully used for other marketed lens products, and packaged lenses are effectively steam sterilized in a validated autoclave. Blister pack containers are labeled with the lens parameters, lot number and product expiration date. The expiration date has been established through stability studies that have assessed the chemical stability of the lens and package integrity (ability to maintain sterility).

Indications for Use

Lotrafilcon B spherical soft contact lenses are indicated for the optical correction of refractive ametropia (myopia and hyperopia) in phakic or aphakic persons with non-diseased eyes and approximately 1.50 diopters of astigmatism that does not interfere with visual acuity.

Lotrafilcon B toric soft contact lenses are indicated for the optical correction of refractive ametropia (myopia and hyperopia) in phakic or aphakic persons with non-diseased eyes and 6.00 diopters (D) or less of astigmatism.

Lotrafilcon B multifocal soft contact lenses are indicated for the optical correction of presbyopia, with or without refractive ametropia (myopia and hyperopia) in phakic or aphakic persons with non-diseased eyes who may require a reading addition of +3.00 diopters (D) or less and have up to approximately 1.50 diopters of astigmatism.

Lotrafilcon B multifocal toric soft contact lenses are indicated for the optical correction of refractive ametropia (myopia, hyperopia) and presbyopia in phakic or aphakic persons with non-diseased eyes and 6.00 diopters (D) or less of refractive and/or corneal astigmatism.

Eye care professionals may prescribe the lenses for daily disposable wear (lenses are discarded upon removal from the eye) or daily wear with removal for cleaning and disinfection (chemical, not heat) prior to reinsertion and frequent replacement, as recommended by the eye care professional.

Brief Summary of Nonclinical Tests and Results

A series of nonclinical tests were performed to demonstrate the substantial equivalence of lotrafilcon B contact lenses packaged with saline additive (modified saline) to the predicate device. All testing was conducted in accordance with the May 1994 FDA guideline titled *Premarket Notification 510(k) Guidance Document for Class II Contact Lenses* and ISO standards, as applicable. Results verify that lenses packaged in modified saline remain non-toxic and biocompatible and have material characteristics comparable to, or better than, other currently marketed soft contact lenses. Results from all tests demonstrate substantial equivalence to the predicate lenses.

A series of nonclinical testing was performed to verify the equivalence of lenses packaged in modified saline to the predicate device. Nonclinical biocompatibility testing was conducted in accordance with the GLP regulation (21 CFR Part 58). The results of all nonclinical testing demonstrate:

- The lens material, lens extracts and package saline of the device in modified saline are equivalent to the predicate and remain non toxic and non-irritating.
- Lens physical and material properties of the device in modified saline are consistent with industry-marketed lenses and equivalent to or better than the predicate lens.

- Like the predicate device, the device in modified saline is compatible with commonly available lens care products.

Substantial Equivalence Comparison and Conclusion

Table 1 provides a side-by-side comparison of the device in modified saline as compared to the predicate device in terms of intended use and technological information.

Table 1 Substantial Equivalence Comparison

	Predicate Devices		**Device in Modified Saline**
Trade Name	**O_2OPTIX®**	**AIR OPTIX® AQUA**	**AIR OPTIX® plus HydraGlyde®**
Submission Number	**K033919/ P010019/S003**	**K073459 / P010019/S008**	*510(k) # to be assigned*
Device Classification Name	Daily Wear Soft Contact Lens 21 CFR 886.5925 (b) (1)	Same	Daily Wear Soft Contact Lens 21 CFR 886.5925 (b) (1)
	Extended Wear Soft Contact Lens 21 CFR 886.5925 (b) (2)	Same	--
Intended Use	Vision correction	Same	Same
Wearing Schedule	Daily wear *and extended wear up to six nights*	Same	Daily wear
Replacement Schedule	Up to one month	Same	Same
Material Classification	Group V (silicone hydrogel) soft contact lens material according to ISO 18369-1:2006/ Amd.1:2009	Same	Same
Lens Material	Lotrafilcon B	Same	Same
Surface Treatment	Plasma treated	Same	Same
Manufacturing Method	Double-side molding	Same	Same
Visibility Tint	Copper phthalocyanine blue	Same	Same

Table 1 Substantial Equivalence Comparison

	Predicate Devices		Device in Modified Saline
Lens Designs	Spherical, toric, multifocal, multifocal toric	Same	Same
Power Range	+20.00 to -20.00D	Same	Same
Base Curve Range	8.0 to 9.2 mm	Same	Same
Diameter Range	13.0 to 15.0 mm	Same	Same
Water Content	33%	Same	Same
Refractive Index	1.422	Same	Same
Oxygen Permeability	~110*	Same	Same
Sterilization	Steam sterilization, validated autoclave	Same	Same
Packaging	Global blister pack	Same	Same
Package Storage Saline Solution	Phosphate buffered saline	Phosphate buffered saline with (or without) 1% Copolymer 845	Phosphate buffered saline with 1% Copolymer 845 and 0.04% (400 ppm) ethylene oxide-butylene oxide ($EO_{45}BO_{10}$) copolymer

*Dkc, boundary layer corrected Dk single point coulometric method (barrer units)

Lotrafilcon B soft contact lenses packaged in modified saline are equivalent to the predicate lens and similar to other daily wear soft contact lenses in terms of technological characteristics and intended use. In addition, the lenses may be disinfected using a chemical, not heat, disinfection regimen.

Any differences which may exist between lotrafilcon B soft contact lenses packaged in modified saline and the predicate device or other Group V silicone hydrogel soft contact lenses do not adversely affect the safety and effectiveness of the device.