



Food and Drug Administration
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January 20, 2016

Alcon Laboratories, Inc.
Dr. Andreas Friese
Principal Regulatory Specialist
6201 South Freeway
Fort Worth, TX 76134-2099

Re: K153643
Trade/Device Name: Focus[®] DAILIES[®], Focus[®] DAILIES[®] Toric, Focus[®] DAILIES[®]
Progressives Soft (hydrophilic) Contact Lens for Daily Wear
Regulation Number: 21 CFR 886.5925
Regulation Name: Soft (hydrophilic) contact lens.
Regulatory Class: Class II
Product Code: LPL/MVN
Dated: December 18, 2015
Received: December 21, 2015

Dear Dr. Friese:

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"

(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 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)

K153643

Device Name

Focus® DAILIES®, Focus® DAILIES® Toric, Focus® DAILIES® Progressives

Indications for Use (Describe)

Focus® DAILIES® and Focus® DAILIES® Toric (nelfilcon A) One-Day soft contact lenses are indicated for daily wear for the optical correction of refractive ametropia (myopia, hyperopia and astigmatism) in not-aphakic persons with non-diseased eyes.

Focus® DAILIES® Progressives (nelfilcon A) One-Day soft contact lenses are indicated for daily wear for the optical correction of refractive ametropia (myopia or hyperopia) and/or presbyopia in not-aphakic persons with non-diseased eyes who require a reading addition of +3.00 diopters (D) or less and who may have 2.00 diopters (D) or less of astigmatism that does not interfere with visual acuity.

The lenses are to be prescribed for single use daily disposable wear. The lenses are not intended to be cleaned or disinfected and should be discarded after a single use.

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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Ink Shelf Life Change

510(k) Summary

1. Submitter Information:

Company: Alcon Laboratories, Inc.
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Date Prepared: 12 October 2015

2. Device Name:

Common Name: Soft Contact Lens
Trade/Proprietary Name: Focus[®] DAILIES[®], Focus[®] DAILIES[®] Toric,
Focus[®] DAILIES[®] Progressives
Classification Name: Daily Wear Soft (Hydrophilic) Contact Lens
Device Classification: Class II [21 CFR 886.5925 (b) (1)]

3. Predicate Device:

Focus[®] DAILIES[®], Focus[®] DAILIES[®] Toric, Focus[®] DAILIES[®] Progressives (nelfilcon A) contact lenses (cleared under K083216) have been identified as predicate device.

4. Description of Device:

The lens material is 69% water and 31% nelfilcon A polymer (polyvinyl alcohol partially acetalized with N-formylmethyl acrylamide). For VISITINT[®] lenses, the color additive phthalocyanine blue (also known as copper phthalocyanine) is added to the lens material to create a light blue edge to edge color to make them easier to see

when handling. The lenses may be printed with inks containing one or more of the following color additives: phthalocyanine blue, phthalocyanine green.

Nelfilcon A lens designs include spherical, toric and multifocal lenses in the following parameter ranges:

| | |
|------------------|---|
| Power Range: | -20.00 D to +20.00 D |
| Center Thickness | varies with design and power (0.10 mm for -3.00 D spherical) |

Lenses have the following properties:

| | |
|----------------------|--|
| Refractive index: | 1.38 |
| Light transmittance: | approximately 96 %T |
| Water content: | 69% by weight |
| Oxygen permeability | 26 barrer measured at 35°C (single point Dk-Polarographic method) |

Lenses are supplied sterile in sealed blister packs containing buffered saline. The compatibility and package integrity of the blister-pack packaging system has been demonstrated and successfully used for other Alcon 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).

5. Indications for Use:

Focus[®] DAILIES[®] and Focus[®] DAILIES[®] Toric (nelfilcon A) One-Day soft contact lenses are indicated for daily wear for the optical correction of refractive ametropia (myopia, hyperopia and astigmatism) in not-aphakic persons with non-diseased eyes.

Focus[®] DAILIES[®] Progressives (nelfilcon A) One-Day soft contact lenses are indicated for daily wear for the optical correction of refractive ametropia (myopia or hyperopia) and/or presbyopia in not-aphakic persons with non-diseased eyes who require a reading addition of +3.00 diopters (D) or less and who may have 2.00 diopters (D) or less of astigmatism that does not interfere with visual acuity.

The lenses are to be prescribed for single use daily disposable wear. The lenses are not intended to be cleaned or disinfected and should be discarded after a single use.

6. Substantial Equivalence:

The modification involves using the same print technology already established for the Focus[®] DAILIES[®] family of (nelfilcon A) soft contact lenses as well as for the DAILIES[®] AquaComfort Plus[®] family of (nelfilcon A) soft contact lenses. The following matrix summarizes the characteristics of the modified device as compared to the predicate device.

Table 1: Substantial Equivalence Comparison

| | Modified Device | Predicate Device |
|---|---|---|
| | Focus DAILIES[®] Family (nelfilcon A) One-Day Soft Contact Lens | Focus DAILIES[®] Family (nelfilcon A) One-Day Soft Contact Lens |
| 510(k) number: | TBD | K083216 |
| Intended Use: | Daily Wear, Daily Disposable | Daily Wear, Daily Disposable |
| Material Classification: | FDA Group 2 (>50% H ₂ O, nonionic polymer) | FDA Group 2 (>50% H ₂ O, nonionic polymer) |
| Lens Material: | nelfilcon A | nelfilcon A |
| Water Content: | 69% | 69% |
| Power Range: | +20.00 to -20.00 D | +20.00 to -20.00 D |
| Visibility Tint: | With or without copper phthalocyanine | With or without copper phthalocyanine |
| Manufacturing Method: | Lightstream [®] Technology: Full mold cast, integrated print step | Lightstream [®] Technology: Full mold cast, integrated print step |
| Lens Designs: | Spherical, toric, multifocal | Spherical, toric, multifocal |
| Sterilization: | Steam sterilization, validated autoclave | Steam sterilization, validated autoclave |
| Packaging: | Blister pack | Blister pack |
| Package Storage Saline Solution: | Phosphate-acetate buffered saline with up to 0.5% Poloxamer 108. | Phosphate-acetate buffered saline with up to 0.5% Poloxamer 108. |

Non-clinical Testing:

A successful process validation was performed on the modified device to verify equivalence of the device to the predicate device. This resulted in the acceptance criteria being met.

Clinical Testing:

The scope of the device modification did not require clinical testing to establish safety and effectiveness of the modified device.

Substantial Equivalence:

Focus[®] DAILIES[®], Focus[®] DAILIES[®] Toric, and Focus[®] DAILIES[®] Progressives (nelfilcon A) One-Day Contact Lenses are substantially equivalent to the predicate lenses and similar to other daily wear soft contact lenses in terms of water content (69% water) and ionic characteristics (FDA Group II: high water, nonionic), and indications for use.

Any differences which may exist between the Focus[®] DAILIES[®], Focus[®] DAILIES[®] Toric, and Focus[®] DAILIES[®] Progressives (nelfilcon A) One-Day Contact Lenses and other Group II soft hydrophilic contact lenses do not adversely affect the safety and effectiveness of the device.