FEB 2 1 2013

Nelfilcon A Soft Contact Lenses
510(k) Summary of Safety and Substantial Equivalence

510(k) Summary: K123994

1. Submitter Information:

Company: CIBA Vision Corporation
11460 Johns Creek Parkway
Duluth, Georgia USA 30097

Contact Person: Martina Heim, PhD, RAC
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Date Prepared: 11-Feb-2013

2. Device Name:

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

3. Predicate Device:

DAILIES® AquaComfort Plus® (nelfilcon A) contact lenses (cleared under K072777) and FOCUS® DAILIES® (nelfilcon A) lenses with print marks (cleared under K083216) have been identified as predicate devices for this Premarket Notification.

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

Lenses have the following properties:

- Refractive index: 1.38
- Light transmittance: ≥ 92% (@ 610 nm)
- 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 CIBA Vision 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). Shelf-life studies are ongoing to further confirm the labeled expiration date.

5. Indications for Use:

DAILIES® AquaComfort Plus® (nelfilcon A) One-Day Contact Lenses are indicated for daily wear for the optical correction of refractive ametropia (myopia and hyperopia) in not-aphakic persons with non-diseased eyes with up to approximately 1.50 diopters (D) of astigmatism that does not interfere with visual acuity.

DAILIES® AquaComfort Plus® Toric (nelfilcon A) One-Day 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 with 6.00 diopters (D) or less of astigmatism.

DAILIES® AquaComfort Plus® Multifocal (nelfilcon A) One-Day 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.

DAILIES® (nelfilcon A) One-Day Contact 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. Description of Safety and Substantial Equivalence:

The modification involves using the same print technology already established for the FOCUS DAILIES family of (nelfilcon A) soft contact lenses 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 devices:

Table 1. Substantial Equivalence Comparison

	Modified Device	**Predicate Device**	**Predicate Device**
	DAILIES® AquaComfort Plus® Family	**DAILIES® AquaComfort Plus® Family**	**FOCUS® DAILIES® Family**
510(k) number	**K123994**	**K072777**	**K083216**
Intended Use	Daily Wear, Daily Disposable	Daily Wear, Daily Disposable	Daily Wear, Daily Disposable
Material Classification:	FDA Group 2 (> 50% H_2O, nonionic polymer)	FDA Group 2 (> 50% H_2O, nonionic polymer)	FDA Group 2 (> 50% H_2O, nonionic polymer)
Lens Material:	nelfilcon A	nelfilcon A	nelfilcon A
Water Content:	69%	69%	69%
Power Range:	+20.00 to -20.00D	+20.00 to -20.00D	+20.00 to -20.00D
Visibility Tint:	With or without copper phthalocyanine	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	Lightstream® Technology: Full mold cast, integrated print step
Lens Designs:	Spherical, toric, multifocal	Spherical, toric, multifocal	Spherical, toric, multifocal
Sterilization:	Steam sterilization, validated autoclave	Steam sterilization, validated autoclave	Steam sterilization, validated autoclave
Packaging:	Blister pack	Blister pack	Blister pack
Package Storage saline solution	Phosphate-acetate buffered saline with up to 0.05% Poloxamer 108. Contains PEG and HPMC.	Phosphate-acetate buffered saline with up to 0.05% Poloxamer 108. Contains PEG and HPMC.	Phosphate-acetate buffered saline with up to 0.02% Poloxamer 108

Non-clinical Testing:

A series of non-clinical testing was performed to verify equivalence of the device to the predicate device. Non-clinical biocompatibility testing was conducted in accordance with the GLP regulation (21 CFR Part 58).

The results of all non-clinical testing demonstrate:

- Physicochemical characteristics of the device are substantially equivalent to the predicate lens.
- The lens material and extracts of the device are substantially equivalent to the predicate device and are non toxic and non-irritating.

Successful stability testing supports the labeled expiration date.

Clinical Testing:

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

Substantial Equivalence:

The DAILIES® AquaComfort Plus®, DAILIES® AquaComfort Plus® Toric, and DAILIES® AquaComfort Plus® Multifocal (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 DAILIES® AquaComfort Plus®, DAILIES® AquaComfort Plus® Toric, and DAILIES® AquaComfort Plus® Multifocal (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.

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

February 21, 2013

Ciba Vision Corporation
% Martina Heim, Ph.D., RAC
Senior Regulatory Specialist
11460 Johns Creek Parkway
Duluth, GA 30097

Re: K123994
Trade/Device Name: DAILIES® AquaComfort Plus®, DAILIES® AquaComfort Plus® Toric, DAILIES® AquaComfort Plus® Multifocal
Regulation Number: 21 CFR 886.5925 (nelfilcon A)
Regulation Name: Soft (hydrophilic) contact lens
Regulatory Class: Class II
Product Code: LPL, MVN
Dated: December 21, 2012
Received: December 26, 2012

Dear Dr. Heim:

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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

Indications for Use

510(k) Number (if known): **K123994**

Device Name: DAILIES® AquaComfort Plus®, DAILIES® AquaComfort Plus® Toric, DAILIES® AquaComfort Plus® Multifocal

Indications For Use:

DAILIES® AquaComfort Plus® (nelfilcon A) One-Day Contact Lenses are indicated for daily wear for the optical correction of refractive ametropia (myopia and hyperopia) in not-aphakic persons with non-diseased eyes with up to approximately 1.50 diopters (D) of astigmatism that does not interfere with visual acuity.

DAILIES® AquaComfort Plus® Toric (nelfilcon A) One-Day Contact Lenses are indicated for daily wear for the optical correction of refractive ametropia (myopia and hyperopia) in not-aphakic persons with non-diseased eyes with 6.00 diopters (D) or less of astigmatism.

DAILIES® AquaComfort Plus® Multifocal (nelfilcon A) One-Day 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 may 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.

DAILIES® (nelfilcon A) One-Day Contact 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.

Prescription Use __X__ (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 CDRH, Office of Device Evaluation (ODE)

Kesia Y. Alexander -S
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(Division Sign-Off)
Division of Ophthalmic and Ear, Nose and Throat Devices
510(k) Number **K123994**