| CIBA Vision. A Novartis Company | CIBA Vision® Corporation<br>11460 Johns Creek Parkway<br>Duluth, GA USA 30097 | Page 1 of 3 |
|---|---|---|
| **Focus® DAILIES® (nelfilcon A) ONE-DAY Soft Contact Lens Parametric Release** | | |
| 510(k) Summary of Safety and Effectiveness | | |

K992446

**510(k) Summary**

## 1. Submitter Information:

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|---|---|
| Company: | CIBA Vision Corporation<br>11460 Johns Creek Parkway<br>Duluth, Georgia USA 30097 |
| Contact Person: | Alicia M. Plesnarski, RAC<br>Senior Specialist, Global Regulatory Affairs |
| Telephone:<br>FAX: | 678-415-3924<br>678-415-3033 |
| Date Prepared: | July 21, 1999 |

## 2. Device Name:

- Common Name: Soft Contact Lens
- Trade/Proprietary Name: Focus® DAILIES® ONE-DAY CONTACT LENS (nelfilcon A)
- Classification Name: Daily Wear<br>Soft (hydrophilic) Contact Lens
- Device Classification: Class II {21 CFR 886.5925 (b) (1)}

## 3. Predicate Device(s):

CIBA Vision's Focus® DAILIES® (nelfilcon A) One-Day Contact Lens
Clear lenses: K943487
VISITINT® lenses: K984273

## 4. Description of Device:

The DAILIES® (nelfilcon A) ONE-DAY CONTACT LENS is a daily wear soft contact lens intended for single use daily disposable wear. The lens material is 69% water and 31% nelfilcon A polymer (polyvinyl alcohol partially acetalized with N-formylmethyl acrylamide).

Lenses are supplied sterile in foil sealed blister packs containing isotonic phosphate-acetate buffered saline solution.

## 5. Indications for Use:

DAILIES® (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.

DAILIES® (nelfilcon A) ONE-DAY CONTACT LENSES are to be prescribed for single use Daily Disposable Wear. DAILIES® lenses are not intended to be cleaned or disinfected and should be discarded after a single use.

## 6. Description of Safety and Substantial Equivalence

### 6.1 Comparison to Predicate Device:

Design, material, chemical composition, manufacturing process, packaging and the sterilization method and cycle remain unchanged from description in cleared Premarket Notification 510(k) K963487 and K984273.

### 6.2 Clinical Testing:

Not conducted for quality assurance procedural change. Lenses remain unchanged from device described and approved in Premarket Notification 510(k) K963487 and K984273.

### 6.3 Non-clinical Testing:

Dailies lenses will continue to be manufactured as previously described in Premarket Notification 510(k) K963487 and K984273. The lens design, production process, packaging materials, finished product specifications and sterilization method and cycle remain unchanged. The only change involves the elimination of Biological Indicators as a sterilization release criteria. Having demonstrated controlled and validated sterilization conditions, verification through monitoring of physical operating parameters for the sterilizer to meet specifications becomes the mechanism for sterility release.

- Validation of the Steam Sterilization Process:
  A successful sterilization cycle includes a chamber temperature of 121 to 124°C for 45 consecutive minutes, with chamber pressure of 2.6 ± 0.2 bar. The sterilization cycle is based on an overkill approach, delivering sufficient lethality to provide a minimum 12-log reduction of microorganisms and at least a $10^{-6}$ probability of microbial survival regardless of the number and heat resistance of the naturally occurring microorganisms. The typical sterility assurance level (SAL) obtained during the execution of a validation study is consistently greater than $10^{-32}$.

- Assessment of Bioburden Levels for Packaged Product:
  Results obtained from measurement of product bioburden over a 4-month period demonstrate production bioburden levels are well controlled. The average presterilization bioburden results were consistently below both 1000 vegetative CFU and 20 spore forming CFU.

**6.4 Ongoing controls and monitoring**

Each sterilization cycle will continue to be verified through monitoring and documented verification of autoclave equipment operating parameters. All relevant related equipment is appropriately calibrated and maintained. Revalidation of the sterilization autoclave is performed annually to verify and ensure consistent operation and sterilization effectiveness. Ongoing monitoring of product bioburden is conducted to ensure low and consistent bioburden levels in the production environment are maintained.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 18 1999

Ms. Alicia M. Plesnarski, Senior Specialist
Global Regulatory Affairs
CIBA Vision Corporation
11460 Johns Creek Parkway
Duluth, Georgia 30097-1556

Re: K992446
Trade Name: Focus® DAILIES® (nelfilcon A) One Day Soft Contact Lens
(Parametric Release)
Regulatory Class: II
Product Code: 86 MVN
Dated: July 21, 1999
Received: July 22, 1999

Dear Ms. Plesnarski:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

A. Ralph Rosenthal, M.D.
Director
Division of Ophthalmic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

## PART III. INDICATIONS FOR USE STATEMENT

**510(k) Number:** K

**Device Name:** CIBA Vision® Focus® DAILIES® (nelfilcon A) One-Day Contact Lens

**Indications For Use:**

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

Eye care practitioners may prescribe the lens for single-use daily disposable wear. DAILIES (nelfilcon A) lenses are not intended to be cleaned or disinfected and should be discarded after a single use.

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**Concurrence of CDRH, Office of Device Evaluation (ODE)**

Myra Smith

(Division Sign-Off)
Division of Ophthalmic Devices
510(k) Number K 992446

**Prescription Use:** ☒ or **Over the Counter Use** ☐