JAN 25 1999

K984273

510(k) SUMMARY

SUMMARY OF SAFETY AND EFFECTIVENESS
FOR
Focus® DAILIES® Visitint® (nelfilcon A) ONE-DAY CONTACT LENSES

1. **Submitter Information**

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

Contact Person: Steven Dowdley, RAC
Senior Regulatory Affairs Associate
Telephone (770) 418-3897, Fax (770)418-2819

2. **Device Name**

Common Name: Soft Contact Lens
Classification Name: Daily Wear Soft (hydrophilic) Contact Lenses
Proprietary Name: Focus® DAILIES® Visitint® (nelfilcon A) ONE-DAY CONTACT LENSES
Device Classification: Class II {21CFR 886.5925(b)(1)}

3. **Predicate Devices**

The clear (non-tinted) Focus® DAILIES® (nelfilcon A) ONE-DAY CONTACT LENS was selected as the predicate device for Focus® DAILIES® Visitint® (nelfilcon A) ONE-DAY CONTACT LENS. The predicate was selected because of the material and the intended use.

4. **Description of Device:**

The Focus® DAILIES® Visitint® (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). The lenses are made by incorporating a color additive ([phthalocyaninato (2-)] copper) into the nelfilcon polymer. The lenses are tinted for visibility purposes to make them easier to see when handling.

Focus® DAILIES® Visitint® (nelfilcon A) ONE-DAY CONTACT LENSES are available in a spherical lens design of the following dimensions.

- Chord Diameter: 13.8
- Center Thickness: 0.09 to 0.17 mm (0.10 at -3.00)
- Base Curve: 8.6 mm
- Powers: +4.00D to -6.00D (0.25D steps)
  -6.50D to -8.00D (0.50D steps)

A lens has the following properties:

- Specific gravity: 1.06
- Refractive index: 1.38 (hydrated)
- Light transmittance: 96%
- Water content : 69% by weight in normal saline
- Oxygen permeability 26 x 10-11{(cm 2/sec)(ml O2 /ml·mmHg)} at 35°C (Fatt corrected).

Lenses are supplied sterile in foil sealed blister packs containing isotonic buffered saline solution. The packaging components have tested non-toxic when evaluated in *in-vitro* and *in-vivo* laboratory studies, and packaged lenses are effectively steam sterilized in a validated autoclave. Blister packs 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). Stability study data currently supports a twenty-four (24) month shelf-life for Focus® DAILIES® Visitint® (nelfilcon A) ONE-DAY CONTACT LENSES in foil packaging. Shelf-life studies are ongoing to determine extension of expiration dating.

5. Indications for Use:

Focus® DAILIES® Visitint® 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.

Focus® DAILIES® Visitint® ONE-DAY CONTACT LENSES are to be prescribed for single use daily disposable wear. Focus® DAILIES® Visitint® LENSES are not intended to be cleaned or disinfected and should be discarded after a single use.

6. Description of Safety and Substantial Equivalence

A series of non-clinical tests were performed to demonstrate the safety and effectiveness of the Focus® DAILIES® Visitint® ONE-DAY CONTACT LENSES, and establish substantial equivalence to currently marketed, predicate (control) lens. 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 in conformance to applicable device regulations. Results demonstrate the lens is non-toxic and biocompatible, and has material characteristics comparable to other currently marketed soft contact lenses.

Non-Clinical Testing:

A series of in vitro and in vivo non-clinical toxicology and biocompatibility testing was performed to assess the safety and effectiveness of the contact lens. All non-clinical toxicology tests were conducted in accordance with the GLP regulations (21CFR Part 58).

The results of the non-clinical testing on the Focus® DAILIES® Visitint® ONE-DAY CONTACT LENSES demonstrate that:

- The lens material is not toxic and the extracts are non-irritating.
- Extracts of the lenses do no show the presence of residual lens starting material.
- Lens physical and material properties are consistent with the currently marketed Focus® DAILIES® ONE-DAY CONTACT LENSES.
- The lens material remains unaffected, with respect to lens properties, by exposure to peroxide disinfection systems and other marketed chemical lens care disinfectant systems.

7. **<u>Substantial Equivalence</u>**

The Focus® DAILIES® Visitint® ONE-DAY CONTACT LENS is substantially equivalent to the clear (non-tinted) version of Focus® DAILIES® Visitint® ONE-DAY CONTACT LENS in terms of material, water content, Dk values, ionic characteristics, and indications for use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 25 1999

Mr. Steven Dowdley
Senior Associate, Regulatory Affairs
CIBA Vision Corporation
11460 Johns Creek Parkway
Duluth, Georgia 30097

Re: K984273
Trade Name: Focus ® DAILIES ® VISITINT® (nelfilcon A) ONE - DAY CONTACT LENSES
Regulatory Class: II
Product Code: 86 MVN
Dated: November 24, 1998
Received: November 30, 1998

Dear Mr. Dowdley:

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

INDICATIONS FOR USE STATEMENT

510(K) Number: K984273

Device Name: Focus® DAILIES® Visitint® (nelfilcon A) ONE-DAY CONTACT LENSES

Indications For Use (including toric lens for astigmatism):

Focus® DAILIES® Visitint® (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.

Focus® DAILIES® Visitint® (nelfilcon A) ONE-DAY CONTACT LENSES are to be prescribed for single use daily disposable wear. Focus® DAILIES® Visitint® LENSES are not intended to be cleaned or disinfected and should be discarded after a single use.

Alternate Indications For Use (spherical lens only):

Focus® DAILIES® Visitint® (nelfilcon A) ONE-DAY CONTACT LENSES are indicated for daily wear for the optical correction of refractive ametropia in not-aphakic persons with non-diseased eyes who are myopic or hyperopic and may have minimal astigmatism that does not interfere with visual acuity.

Focus® DAILIES® Visitint® (nelfilcon A) ONE-DAY CONTACT LENSES are to be prescribed for single use daily disposable wear. Focus® DAILIES® Visitint® LENSES are not intended to be cleaned or disinfected and should be discarded after a single use.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use: X or Over-the-counter:

(Division Sign-Off)
Division of Ophthalmic Devices
510(k) Number K984273