

FEB 23 2000

Summary of 510(k) Submission

K 994324

**Name and
address of
submitter**

Vistakon, Johnson & Johnson Vision Products, Inc.
7500 Centurion Parkway
Jacksonville, Florida 32256
Contact: Sharon Briggs
Phone: (904) 443-1471
Date Prepared: December 21, 1999

**Identification of
device**

- The trade name is ACUVUE (etafilcon A) soft (hydrophilic) contact lenses, clear and visibility tinted, with UV blocker, for daily wear
 - The common or usual name is Soft (hydrophilic) Contact Lens (daily wear).
 - The FDA Classification is Class II.
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**Predicate
devices**

The predicate device is ACUVUE (etafilcon A) soft (hydrophilic) contact lenses, clear and visibility tinted, with UV blocker, for daily wear covered under K991134.

**Description of
device**

The device description does not change from that cleared under K991134.

Continued on next page

Summary of 510(k) Submission, Continued

Indications for Use

The ACUVUE Contact Lens (spherical) is indicated for daily wear for the correction of refractive ametropia (myopia and hyperopia) in aphakic or non-aphakic persons with non-diseased eyes who may have 1.00 D or less of astigmatism.

The ACUVUE BIFOCAL Contact Lens is indicated for daily wear for the correction of distance and near vision in presbyopic, aphakic or non-aphakic persons with non-diseased eyes who may have 0.75 D or less of astigmatism.

The ACUVUE TORIC Contact Lens is indicated for daily wear for the correction of visual acuity in aphakic or non-aphakic persons with non-diseased eyes that are hyperopic or myopic and may have 10.00 D or less of astigmatism.

The ACUVUE TORIC BIFOCAL Contact Lens is indicated for daily wear for the correction of distance and near vision in presbyopic aphakic or non-phakic persons with non-diseased eyes who may have 10.00 D of astigmatism or less.

ACUVUE Contact Lenses help protect against transmission of harmful UV radiation to the cornea and into the eye.

Eye care practitioners may prescribe the lens for either single-use disposable wear or for frequent/planned replacement wear, with cleaning, disinfection and scheduled replacement. When prescribed for frequent/planned replacement wear, the lens may be disinfected using a chemical disinfection system only.

Summary of 510(k) Submission, Continued

Reason for 510(k) The reason for the 510(k) is to revise the "Wear Schedule" in the Draft Package Insert, and the "Introduction" statements in the Draft Patient Instruction Guides (Disposable and Frequent Replacement) for ACUVUE (etafilcon A) soft (hydrophilic) contact lenses, clear and visibility tinted, with UV blocker, for daily wear to include the following statement:

When ACUVUE UV Blocking Contact Lenses are replaced at intervals ranging from 1 day to 2 weeks, the risk of developing giant papillary conjunctivitis may be reduced .

Characteristics The characteristics do not change. They are the same as previously submitted in K991134.

Non-clinical studies Non-clinical studies (chemistry, toxicology, microbiology, shelf-life, and leachability) on the lens material were not conducted because the lens material, etafilcon A, does not change.

Clinical studies This 510(k) describes a labeling modification which is supported by clinical studies published in the July 1999 CLAO Journal (see Attachment A). There is no change in lens material, the manufacturing process, nor the parameters and properties, therefore, the clinical data previously submitted in K991134 supports the clinical safety of the subject device.

Conclusions drawn from studies Additional studies were not conducted, therefore, the conclusions drawn from studies previously submitted in K991134 support the non-clinical and clinical safety of the subject device. The clinical studies published in the July 1999 CLAO Journal support the labeling modification that is the subject of this 510(k).



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Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Sharon A. Briggs
Manager, Regulatory Submissions
VISTAKON™
7500 Centurion Parkway
Jacksonville, FL 32256

Re: K994324
Trade Name: ACUVUE (etafilcon A) Soft (hydrophilic) Contact Lens Clear and Visibility
Tinted with UV blocker
Regulatory Class: II -
Product Code: 86 LPL
Dated: December 21, 1999
Received: December 22, 1999

Dear Ms. Briggs:

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

