APR 1 3 2005

510(k) Summary

K050743

Applicant Information

Date prepared:	March 21, 2005
Name:	Unilens Corp., USA
Address:	10431 72nd Street, North Largo, FL 33777
Contact person:	Josepha Bruno, Director Quality Assurance
Phone number:	(727) 544-2531 x306
Fax number:	(727) 545-1883

Device Information

Device classification:	Class II
Classification number:	LPL
Classification name:	Lenses, Soft Contact, Daily Wear
Trade name:	Aquaflex 2 (tefilcon) Soft (hydrophilic) Contact Lens

Equivalent device

The Aquaflex 2 (tefilcon) Soft (hydrophilic) Contact Lens for Daily Wear is substantially equivalent to the predicate device identified below in terms of intended use and design.

Predicate device:
BayVue (polymacon) Soft (hydrophilic) Contact Lens

Device description

The Aquaflex 2 (tefilcon) Soft (hydrophilic) Contact Lens is available as a spherical lens. The lens material, tefilcon, is a hydrophilic polymer of 2-hydroxyethyl methacrylate crosslinked with ethylene glycol dimethacrylate.

The Aquaflex 2 Contact Lens is a hemispherical shell of the following dimensions:

Chord diameters	12.5 to 17.0mm
Center thickness	varies with power; Standard design 0.10 mm to 0.56 mm and Superthin design 0.05 mm to 0.39 mm
Base curves	7.0 to 10.5mm
Powers	-20.00 to +20.00D
Optical zone diameters	5.0 to 10.0mm

The physical/optical properties of the lens are:

specific gravity	1.18
refractive index (wet)	1.43
light transmittance	98%
water content	37.5%
oxygen permeability	8.9×10^{-11} (cm/sec)(ml O_2/ml x mm Hg), measured at 21°C (Fatt Method)

Intended use

The Aquaflex 2 Contact Lens is indicated for daily wear for the correction of refractive ametropia (myopia and hyperopia) and astigmatism up to 1.50 diopters or less in aphakic and/or not-aphakic persons with non-diseased eyes. The lens may be disinfected using either a heat or chemical disinfection system.

Substantial equivalence

The new device will be manufactured according to specified process controls and a quality management system currently in place. The device will undergo manufacturing, packaging and sterilization procedures similar to devices currently manufactured, marketed and distributed by Unilens Corp., USA. The established safety profile (pre-clinical toxicology and manufacturing/chemistry data) of the device is equivalent to the LL-Bifocal (tefilcon) Contact Lens, 510(k) K971647. Being similar with respect to indications for use, materials, physical construction and safety and effectiveness to the predicate device, this meets the requirements per section 510(k) of the act regarding substantial equivalence and *does not raise* different questions of safety and effectiveness than the predicate device identified above.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 13 2005

Unilens Corp., USA
c/o Josepha Bruno
Director, Quality Assurance
10431 72nd Street North
Largo, FL 33777

Re: K050743
Trade/Device Name: Aquaflex 2 (tefilcon) Soft (hydrophilic) Contact Lens
Regulation Number: 21 CFR 886.5925
Regulation Name: Soft (hydrophilic) Contact Lens
Regulatory Class: Class II
Product Code: LPL
Dated: March 21, 2005
Received: March 21, 2005

Dear Ms. Bruno:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), 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 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); 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.

This letter will allow you to begin marketing your device as described in your Section 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), please contact the Office of Compliance at (301) 827-8910. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

David M. Whipple
Acting 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): k050743

Device Name: Aquaflex 2 (tefilcon) Soft (Hydrophilic) Contact Lens

Indications for Use:

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(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X AND/OR Over-The-Counter-Use
(Part 21 CFR 801 Subpart D) (Part 21 CFR 807 Subpart C)

Daniel W. C. Brown, Ph.D.

(Division Sign-Off)
Division of Ophthalmic Ear,
Nose and Throat Devises

510(k) Number K050743