



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 2 5 2005

Hydron Limited
c/o Mr. J.B. Holloway
Head of Quality and Regulatory Affairs
Hawley Lane
Farnborough
Hampshire GU14 8EQ
United Kingdom

Re: K983160

Trade/Device Name: ActiToric (ocufilcon A) Hydrophilic Toric Contact Lens for
Daily Wear

Regulation Number: 886.5925

Regulation Name: Lenses, Soft Contact, Daily Wear

Regulatory Class: II

Product Code: LPL

Dated: January 8, 1999

Received: January 11, 1999

Dear Mr. Holloway:

This letter corrects the product code in our substantially equivalent letter of February 18, 1999.

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 (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 additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In

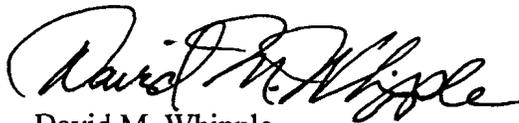
addition, FDA may publish further announcements concerning your device in the Federal Register.

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 continue 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 (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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/dsma/dsmamain.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

510(k) Number (if known): K 983160

Device Name: Hydron ActiToricon(ocufilcon A) Soft (Hydrophilic) Toric Contact Lens for Daily Wear .

Indications For Use:

The Hydron ActiToricon(ocufilcon A) Soft (Hydrophilic) Toric Contact Lens is indicated for daily wear for the correction of reactive ametropia (myopia, hyperopia and astigmatism) in aphakic and non-aphakic persons with non-diseased eyes that may exhibit refractive and/or corneal astigmatism up to 2.50 diopters.

Eyecare practitioners may prescribe the lens for planned frequent replacement wear, with cleaning, disinfection and replacement. The lens may be disinfected using either a heat, chemical or hydrogen peroxide disinfection system.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Karen W. Winters

(Division Sign-Off)
Division of Ophthalmic Devices

510(k) Number K983160



(Optional Format 3-10-98)

Prescription Use
(Per 21 CFR 801.109)

OR

Over-The-Counter Use

(Optional Format 1-2-96)

2/18/99

K983160

510(k) SUMMARY FOR ACTITORIC SOFT (HYDROPHILIC) TORIC CONTACT LENS

K NUMBER: 983160

APPLICANT INFORMATION:

Date Prepared: January 1999

Company Name: Hydron Limited

Company Address: Hawley Lane
Farnborough
Hants
GU14 8EQ
United Kingdom

Contact Person: Julian Holloway
Head of Quality Assurance and Regulatory Affairs

Phone No: 011 44 1252 554500
Fax No: 011 44 1252 544040

DEVICE INFORMATION:

Regulatory Classification: Class II – Ophthalmic devices

Trade Name: ActiToric (ocufilcon A)

Classification Name: Soft (Hydrophilic) Toric Contact Lens for Daily Wear.

EQUIVALENT DEVICE:

Hydron ActiToric (ocufilcon A) Soft (Hydrophilic) Toric Contact Lens for Daily Wear is equivalent to Specialty UltraVision Specialty T (ocufilcon A) Toric Soft (Hydrophilic) Contact Lens for Daily Wear approved by the FDA under 510(k) application K963764, Jan. 1997.

ActiToric (ocufilcon A) Soft (Hydrophilic) Toric Contact Lens for Daily Wear is substantially equivalent to the indication for use of the Specialty T (ocufilcon A) Soft (Hydrophilic) Toric Contact Lens for Daily Wear marketed for use in the US. This lens is in Group 3 ionic, low water content polymers as established by the FDA and located in the Guidance Document for Daily Wear Contact Lenses, Revised Edition May 1994. The physical, optical, and chemical properties of the ActiToric (ocufilcon A) Soft (Hydrophilic) Toric contact Lens for Daily Wear are equivalent to those of the Specialty T (ocufilcon A) Toric Soft (Hydrophilic) Contact Lens for Daily Wear. The subject device utilises the same formulation, manufacturing and sterilisation processes, packaging, Quality Control/Quality Assurance Procedures and established shelf life as the predicate device, the Specialty UltraVision Specialty T (ocufilcon A) Toric Soft (Hydrophilic) Contact Lens for Daily Wear.

A side by side comparison of the physical, optical and mechanical properties establishes the equivalency of these two contact lens products (see Table 2.1).

Table 2.1. Summary of Properties of ActiTorc and the Predicate Device, Specialty T.

Property	ActiTorc	Specialty T
<u>Material:</u>		
USAN Group Monomers	ocufilcon A 3 (ionic) 2-HEMA, MA, EGDMA	ocufilcon A 3 (ionic) 2-HEMA, MA, EGDMA
<u>Manufacturing:</u>		
Process	Spun-cast	Spun-cast
Diameter (mm)	14.5	14.5
Center Thickness (mm)	0.15	0.15
Base curve (mm)	8.95 (equivalent)	8.90 (equivalent)
<u>Physical Properties:</u>		
Refractive Index	1.43 ± 0.001	1.43 ± 0.001
Water content %	45 ± 0.00	45 ± 0.00
Oxygen Permeability*	11.9 ± 1.85 × 10 ⁻¹¹	12.2 ± 1.41 × 10 ⁻¹¹
Light Transmittance %	98 ± 0.4	99 ± 0.4
<u>Mechanical Properties:</u>		
Modulus (N/mm ²)	0.32 ± 0.045	0.33 ± 0.056
Tensile strength (N/mm ²)	0.32 ± 0.116	0.30 ± 0.010
Elongation at break (%)	208 ± 94	186 ± 89

* measured on single lenses Units: (cm² x ml O₂)/(sec x ml x mmHg)

DESCRIPTION OF THE DEVICE:

The ActiTor^{ic} soft contact lens is a hemispherical shell manufactured of polymerised material of HEMA and other monomeric ingredients crosslinked with EGDMA and other components which yield the appearance of a lens which is designed to fit over the corneal surface of the eye. This lens is designed with varying base curves which conform to the shape of the radius of the cornea and centre over the apex of the cornea to provide corrective refraction for functional conditions of the eye including myopia (near-sightedness), hyperopia (farsightedness) and astigmatism (multiple foci). The lens provides corrective power which is to correspond to the refractive power of the eye to which it is being treated. The lens has an aspheric base curve that is formed in the free surface during the spinning process. Secondary and tertiary curves as well as bevelled edge configurations are built into the lens for the purpose of aiding in lens centration and comfort. The lens is manufactured by spin casting and has a front toric surface which is determined by the shape of the mould to provide consistent optics. Orientation marks are moulded into the front surface as part of the spin casting process. The lens is a prism ballasted, non-truncated toric, with an inferior slab off to help maintain patient comfort. Axis stabilisation is achieved by the action of the lids on the differential thickness profile (prism) of the lens squeezing the thicker portion of the lens to the bottom.

INDICATIONS FOR USE:

Device Name: Hydron ActiTor^{ic} (ocufilcon A) Soft (Hydrophilic) Toric Contact Lens for Daily Wear.

The Hydron ActiTor^{ic} (ocufilcon A) Soft (Hydrophilic) Toric Contact Lens is indicated for daily wear for the correction of refractive ametropia (myopia, hyperopia and astigmatism) in aphakic and not-aphakic persons with non-diseased eyes that may exhibit refractive and/or corneal astigmatism up to 2.50 diopters.

Eyecare practitioners may prescribe the lens for frequent/planned replacement wear, with cleaning, disinfection and replacement. The lens may be disinfected using either a heat, chemical or hydrogen peroxide disinfection system.

TECHNICAL SUMMARY:

1. Toxicology

All necessary toxicology studies were undertaken and results were within normal limits.

2. Microbiology

Relevant test procedures have been undertaken and are included with this 510(k) notification.

3. Compatibility

Compatibility testing is not required as recommended lens care products have been approved for the same lens material (ocufilcon A).

4. Lens Stability

Lens stability testing indicates that the ActiTorc lenses can be stored for a time period of up to 8 years with no adverse effect on the lenses.

5. Clinical

Clinical safety data is not required as the device has the same USAN and method of manufacture as the predicate device.