

DEC 10 1999

510 (k) SUMMARY FOR ACTIFRESH™ 400 SOFT (HYDROPHILIC) CONTACT LENS

K NUMBER: K 983637

APPLICANT INFORMATION:

Date Prepared: 13th October 1998

Company Name: Hydron Ltd

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U.K.

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DEVICE INFORMATION:

Regulatory Classification: Class II – Ophthalmic devices

Trade Name: ActiFresh™ 400 (lidofilcon A)

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

EQUIVALENT DEVICE:

Hydron ActiFresh 400 (lidofilcon A) Soft (Hydrophilic) Contact Lens for Daily Wear is equivalent to Hydron Omniflex SofBlue (lidofilcon A) Hydrophilic Contact Lens for Daily Wear approved by the FDA under PMA application P830047 Suppl 6, April 1991.

ActiFresh 400 (lidofilcon A) Soft (Hydrophilic) Contact Lens for Daily Wear is substantially equivalent to the indication for use of the Hydron Omniflex SofBlue (lidofilcon A) Hydrophilic Contact Lens for Daily Wear. This lens is in Group 2 non-ionic, high 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 ActiFresh 400 (lidofilcon A) Soft (Hydrophilic) Contact Lens for Daily Wear are similar to those of the Hydron Omniflex SofBlue (lidofilcon A) Hydrophilic Contact Lens for Daily Wear. The subject device utilises a material of the same USAN and suffix as the predicate device but incorporates a UV filter, different handling tint and different method of manufacture.

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 ActiFresh 400 and the Predicate Device, Omniflex SofBlue Hydrophilic Contact Lens.

| Property | ActiFresh 400 | Omniflex SofBlue |
|--|------------------------|------------------------------|
| Material: | | |
| USAN | lidofilcon A | lidofilcon A |
| Group | 2 (non-ionic) | 2 (non-ionic) |
| Monomers | nVP, MMA | nVP, MMA |
| Manufacturing: | | |
| Process | Cast Molding | Lathe-cut |
| Diameter (mm) | 14.3 | 14.3 |
| Center Thickness (mm) | 0.12 | 0.12 |
| Base curves (mm) | 8.4, 8.8 | 8.10 to 9.30 |
| Physical Properties: | | |
| Refractive Index | 1.37 ± 0.0003 | 1.39 ± 0.0007 |
| Water content (%) | 73 ± 0.3 | 69 ± 0.5 |
| Oxygen Permeability (Dk)*at 35° | 28 × 10 ⁻¹¹ | 24 ± 2.7 × 10 ⁻¹¹ |
| Light Transmittance (from 385 to 780nm) | 94.11±14.68% | 95.24±3.42% |
| Mechanical Properties: | | |
| Modulus (N/mm ²) | 0.31 ± 0.04 | 0.52 ± 0.065 |
| Tensile strength (N/mm ²) | 0.48 ± 0.14 | 1.01 ± 0.338 |
| Elongation at break (%) | 126 ± 27 | 213 ± 63 |

* measured on single lenses by the original Fatt method. Units: (cm² x ml O₂)/(sec x ml x mmHg)

DESCRIPTION OF THE DEVICE:

The ActiFresh 400 soft contact lens is a hemispherical shell manufactured of a high water content (73%), polymerised material of n-vinyl pyrrolidone (nVP) and methyl methacrylate (MMA) and other components which yield the appearance of a lens which is designed to fit over the corneal surface of the eye. A UV filter has been incorporated into the lens material. The lens is visibility tinted with a minute amount of poly (2-hydroxyethyl methacrylate and Reactive Blue Dye #4 copolymer. The 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) and hyperopia (farsightedness). The lens provides corrective power which is to correspond to the refractive power of the eye to which it is being treated. The lens is designed with a spherical lenticulated front surface and spherical bicurve back surface. The lens is manufactured by cast molding.

INDICATIONS FOR USE:

Device Name: Hydron ActiFresh 400 (lidofilcon A) Soft (Hydrophilic) Contact Lens for Frequent Replacement Daily Wear.

The Hydron ActiFresh 400 (lidofilcon A) Soft (Hydrophilic) Contact Lens is indicated for daily wear for the correction of refractive ametropia (myopia and hyperopia) in aphakic and not-aphakic persons with non-diseased eyes that may exhibit refractive and/or corneal astigmatism up to 2.00 diopters.

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

The lenses are available in the spherical power range of -15.00 to +10.00 diopters.

TECHNICAL SUMMARY:

A range of tests have been carried out to support this submission. They are briefly summarised below.

1. NON CLINICAL

Physical and Mechanical Properties

The refractive indices of the ActiFresh 400 lenses and the predicate device were measured using a calibrated Abbe refractometer. Water content was determined gravimetrically while oxygen permeability was measured using the Fatt method that employs the Clark electrode. Light transmittance was determined using a UV/visible spectrophotometer averaging the results over the range 385 to 780 nm. The mechanical properties were determined from tensile measurements made on samples cut from the lenses. The tests being made with the samples immersed in saline solution. For each test, 30 lenses were measured to obtain the quoted results shown in table 2.1.

Toxicology

Agar overlay toxicity, acute systemic toxicity and acute ocular irritation studies were carried out according to the appropriate ISO standards. All of the results provide reasonable assurance that the ActiFresh 400 lenses are non-toxic.

Microbiology

Lenses are sterilised by steam at 121°C for 15 minutes. The efficacy of the sterilisation process is checked during the validation of the autoclave using biological indicators.

Bioburden testing of pre-sterile product is performed on a weekly basis with levels below 10 cfu/ml to ensure a final SAL of 10^{-6} .

Compatibility

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

Lens Stability

Accelerated shelf life and sterility testing has demonstrated a shelf life of up to 8 years for ActiFresh 400 lenses.

2. CLINICAL

The following summaries give details of the clinical studies undertaken to date with the ActiFresh 400 lens.

- Clinical Evaluation of Cast-Moulded ActiFresh 400 During a 3-month Period of Daily Wear (LIDF-219)
- High Power ActiFresh 400 Study (LIDF-220)
- Comparative Clinical Evaluation of the Hydron ActiFresh 400 Soft Contact Lens (DISP-203).

STUDY OBJECTIVE

The study was designed to evaluate the safety, efficacy, and acceptability of the visibility tinted, cast molded, ActiFresh 400 lens incorporating a UV filter.

STUDY DESIGN

This was a 3-month, 39 subject, open-label, uncontrolled, daily wear, dispensing study. Subjects were equally divided between two groups, each group using a different care system: Oxysept 1-Step or Hydron Multi chemical multi-purpose system.

STUDY LENSES AND LENS CARE REGIMENS

Study lenses were provided in 8.80mm and 8.40mm base curves, 14.3mm diameter, and in powers ranging from +8.00 to -8.00D. Subjects wore the study lenses on a daily wear basis and were assigned to either a chemical or oxidative lens care disinfection system. The following regimens were used:

OXIDATIVE

Allergan Oxysept 1 Step and LC65
Allergan Oxysept Saline

CHEMICAL

Hydron Multi, a multi-purpose system

STUDY POPULATION

A total of 39 (26 females, 13 males) subjects (78 eyes) were enrolled and 38 subjects (76 eyes) were dispensed lenses. Subjects included both new and existing contact lens wearers. Thirty-three subjects (66 eyes) completed the full three months of study lens wear (Table 1). Of the 38 subjects (76 eyes) who had study lenses dispensed, 20 (40 eyes) were assigned a chemical disinfection regimen, and 18 (36 eyes) an oxidative disinfection regimen. Regimen changes during the study were allowed, if necessary; but no subjects required such a change.

RESULTS

Five subjects (10 eyes) were discontinued from the study before completing three-months of lens wear (Table 8). Of the five subjects discontinued, two (4 eyes) were discontinued for reasons unrelated to the study lenses, and three (6 eyes) for reasons related to the study lenses.

Of the 39 qualified subjects (78 eyes), 26 (52 eyes) had previous contact lens wearing experience and 13 (26 eyes) did not. Twenty-five (50 eyes) previous wearing experience was with hydrogel contact lenses and one (2 eyes) with rigid gas permeable (RGP) lenses.

There were significant differences between the two care system user groups with two slit-lamp variables: corneal staining and inferior palpebral follicles. More staining was recorded with the chemical users than the oxidative users. At the baseline visit 32% and 38% of the Hydron Multi and Oxysept 1-step subjects respectively showed some corneal staining. At the 3-month visit 69% of the Hydron Multi eyes and 43% of the Oxysept 1-step eyes showed some corneal staining.

There were no other notable differences in the findings among the two lens care regimens; consequently pooled tabulations are presented for all variables.

DISCUSSION

The safety of the study lens was demonstrated in these studies by the absence of adverse reactions, and the low incidence of clinically significant slit-lamp findings. Only one subject was discontinued with positive slit-lamp findings. The safety of the study lens is also supported by the very low incidence of changes in keratometry, refraction, and best-corrected visual acuity observed after 3-months wear.

The efficacy of the study lens was demonstrated by the high incidence of subjects whose study lens corrected visual acuity after three months of lens wear was within one line of their initial best corrected visual acuity.

The acceptability of the study lenses was demonstrated by the high completion rate and the low incidence of symptoms of discomfort. Furthermore, daily lens wearing times for those who completed the study averaged between 12.1 after adaptation and 12.7 hours per day at the final visit, even with 33% (13/39) new lens wearers in the population.

The incidence of clinically significant slit-lamp findings and symptoms of discomfort in this study was comparable to that observed in the predicate device, OmniFlex SofBlue (PMA P830047), which is lathe-cut, incorporating a different handling tint, and without a UV filter. This suggests that the basic material and design are not adversely affected by the addition of UV filter and different handling tint, or by the different manufacturing process.

CONCLUSION

The results of this study indicate that the cast molded, visibility tinted, ActiFresh 400 lens incorporating a UV filter worn on a daily wear basis is safe, effective, and acceptable when used with chemical or oxidative disinfection regimens.



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Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Hydron, Limited
C/O Julian B. Holloway
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Hawley Lane, Farnborough
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United Kingdom

Re: K983637

Trade Name: ActiFresh™ 400 (lidofilcon A) Soft (Hydrophilic) Contact Lens for Daily Wear
(Cast molded, Visibility tinted, with UV absorber)

Regulatory Class: II

Product Code: LPL

Dated: November 3, 1999

Received: November 11, 1999

Dear Mr. Holloway:

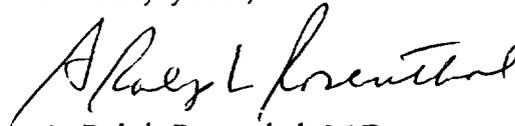
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 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). 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 devices as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your devices to legally marketed predicate devices results in a classification for your devices and thus, permits your devices to proceed to the market.

If you desire specific advice for your devices 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 devices, 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 at (301) 443-6597.

Sincerely yours,



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

Enclosure

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

Concurrence of CDRH, Office of Device Evaluation (ODE)



Karen Warburton

(Division Sign-Off)
Division of Ophthalmic Devices

510(k) Number K983637

(Optional Format 3-10-98)

Prescription Use _____
(Per 21 CFR 801.109)