K 974636

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III. COMPREHENSIVE SUMMARY

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NAME AND USE OF DEVICE

Device Generic Name:	wilofocon A
Device Trade Name:	Flosi rigid gas permeable contact lens
Indications:	Flosi rigid gas permeable contact lenses are indicated for daily wear correction of visual acuity in aphakic and not-aphakic persons with non-diseased eyes who are nearsighted (myopic), farsighted (hyperopic), presbyopic or who have corneal astigmatism.
Airperm Ranges:	Chord diameter 6.5 to 11.5 mm Center thickness 0.05 to 0.70 mm Base Curve 6.50 to 9.00 mm Powers -20.00 to +20.00 diopters
Cleaning and Disinfection:	The Flosi rigid gas permeable contact lens must be disinfected using only a chemical (not heat) disinfection system as recommended.

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VII. DEVICE CHARACTERISTICS

The FLOSI (wilofocon A) Rigid Gas Permeable Contact Lens is available as a spherical, aspherical, and astigmatic (toric) lens. The lens material, wilofocon A, is a fluoro silicone acrylate polymer which contains D & C Green No. 6 as a color additive. The FLOSI (wilofocon A) Contact Lens is a hemispherical shell of the following dimensions:

LENS PARAMETERS AVAILABLE

- Diameter .....6.5 to 11.5 mm
- Center Thickness
  - for Low Minus Lens: .....0.05 to 0.30 mm
  - for Plus Lens: .....0.10 to 0.70 mm
- Base Curve .....6.50 to 9.00 mm
- Powers .....—20.00 to +20.00 Diopters
- Aspheric Lens Eccentricity.....-1.5 to 1.5
  Oblate to Prolate

Peripheral Curves.....0.1 to 10 mm. Flatter or Steeper than Base Curve

- Toric Lens
  - Axis .....1 to 180 degrees in 1 degree steps
  - Cylinder power .....0.50 to 4.00 Diopters

The physical/optical properties of the lens are:

- Specific Gravity.....1.25
- Refractive Index (589 nm at 25°C).....1.44
- Light Transmittance
  - Clear (370-760 nm).....93%
  - Tinted (D & C Green No. 6) (380-780 nm).....87%
- Surface Character.....Hydrophobic
- Wetting Angle (CLMA Method).....23.0 ± 2
- Water Content (Gravimetric method at 22°C).....<1%
- Oxygen Permeability.....Dk 26 x 10^{-11} at 35°C
  (cm^2/sec) (ml O_2 /ml x mmHg) Polarographic method of Fatt (1990)
- Hardness (Shore).....89

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SUMMARY OF STUDIES
FLOSI (wilofocon A) Rigid Gas Permeable Contact Lens

IIIB. PRECLINICAL STUDIES

1. Systemic Injection Test In Mice

The test is based on the FDA guidelines entitled "Testing Guidelines for Class II Contact Lenses, April 1989", and the United States Pharmacopeia XXII, National Formulary XVII. None of the test and control animals exhibited overt signs of toxicity at any of the observation points and hence the test material is considered non-toxic.

2. Eye Irritation Test in Rabbits

The test is based on the FDA guidelines entitled "Testing Guidelines for Class III Contact Lenses, April 1989". The extract of test contact lenses was evaluated for the potential to produce ocular irritation over a 72 hour period. The test article did not cause any significant irritation to the ocular tissues of the test animals.

3. Tissue Culture-Agar Overlay Cytotoxicity Assay

The assay is based on that described in USP and National Formulary. The contact lens blanks did not cause any obsevable cytotoxic effects when tested according to the procedures outlined in the study report and is therefore considered non-cytotoxic.

Based on the results of the preclinical testing it is reasonable to assume that the Flosi (wilofocon) Rigid Gas Permeable Contact Lens Polymer is non-toxic.

IIIC. CLINICAL STUDIES

All eyes enrolled in the study were accounted for. A total of 122 eyes were enrolled in the study. A total of 110 eyes completed a minimum of three months of contact lens wear, 0 eyes were incomplete and 12 eyes were discontinued. The largest number of patients enrolled in this study (92.7%) were previous wearers of rigid gas permeable contact lenses. The average age was 37 years. During the three-month course of this study there were a total of 428 scheduled and 38 unscheduled eye visits.

Slit-Lamp: There was a total of 99 reports of Grade 1 SLFs of which the largest number was for corneal staining (77 reports or 18% of all visits). The staining at the follow-up visits was nearly all of the type three and nine o'clock staining, which was also present at the initial visit. The next most common slit lamp findings were for injection, which included 15 reports or 3.5% of the visits. There were five reports of grade 2 findings, all for staining and which were resolved by lens changes.

The total number of slit-lamp findings were within expecteds for wearers of an RGP contact lens. The large number of reports for corneal staining can be

attributed to the fact that most patients were previous rigid lens wearers who entered the study with three and nine o'clock staining. During the time that lenses were worn by the discontinued patients there were no slit lamp findings reported.

SPCs: There were a total of 135 reports of symptoms, problems or complaints for the 356 eye visits during the three-month course of this study. The largest number of complaints (8.7%) was for variable vision, followed by lens awareness (6.2%). All symptoms, problems or complaints were reduced over time. None of the categories for symptoms, problems, and complaints can be considered outside of the normal expecteds for a rigid gas permeable contact lens.

Keratometry: The majority of the eye meridians (90.4%) showed no change to 0.50 diopters change over the course of this investigation. Changes of 1.00 diopter or less were found in 98.6 percent of the eye meridians. The number of changes were nearly equal for those who had increased or decreased power which resulted in an average change of 0.08 diopters flattening. In the three patients who experienced a change of greater than 1.00 diopter, two eye meridians showed a decrease of 1.25 diopters and one eye meridian showed an increase of 1.25 diopters. The changes in keratometry were generally low and may be attributed to adaptation to a new lens type or usual clinical measurement variation. The three patients who showed changes in one eye meridian of 1.25 diopters all had no change in their normal visual acuity of 20/20 and no significant signs or symptoms.

Refraction: The majority of the eyes (99.1%) showed no change to 1.00 diopters change over the course of this investigation. The number of spherical and cylindrical changes were nearly equal for those who had increased or decreased power, which resulted in an average change of near zero. In the two patients who experienced a change of greater than 1.00 diopter, one (306) showed a spherical change in the left eye of 1.50 diopters. One patient (505) showed a cylindrical decrease in both eyes of 1.50 diopters, which was attributed to a better fit of the test contact lens than was the case for the lens worn prior to the study. The changes in refraction were generally low and may be attributed to a better fitting lens or usual clinical measurement variation. The three eyes that showed changes of 1.50 diopters all had no change in their normal visual acuity of 20/20 and no significant signs or symptoms. For the patients who discontinued, the 12 test eyes showed no change to 0.50 diopters change over the course of this investigation. The number of spherical and cylindrical changes were nearly equal for those who had increased or decreased power. The changes in refractive sphere and cylinder were generally low and may be attributed to normal variation in the findings.

Visual Acuity: A comparison was made between the best corrected visual acuity at the initial examination to the visual acuity when wearing contact lenses at the final examination. There were no patients who experienced a drop of visual acuity that was greater than one line during the course of this study. Two patients had reduced visual acuity both initially and at the end of this study and

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merit comment. Visual acuity results when wearing Flosi Rigid Gas Permeable Contact Lenses during the course of this investigation were found to be within expecteds. No patients experienced a drop of visual acuity that was greater than one line.

The average wearing time achieved at the end of the study was 14.9 hours.

Conclusion:
There were no eyes that experienced adverse reactions, SLFs requiring treatment or SPCs requiring treatment. The FLOSI rigid gas permeable contact lens was shown to be worn safely by all patient eyes in this study including those that completed (110 eyes) and discontinued (12 eyes) the study.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 30 1998

Dr. William Platt
Futuristic Design Associates
1 Avalon Road
Mount Vernon, OH 43050

Re: K974636
Trade Name: Flosi (Wilofocon A) Rigid Gas Permeable Contact Lenses for Daily Wear (Spherical, Aspheric, Toric and Bifocal) Clear and Tinted (with D&C Green #6)
Regulatory Class: II
Product Code: 86 HQD
Dated: March 11, 1998
Received: March 12, 1998

Dear Dr. Platt:

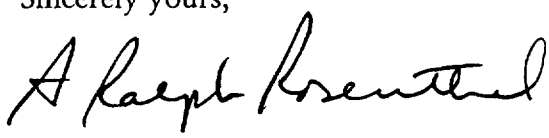
We have reviewed your Section 510(k) notification of intent to market the devices referenced above and we have determined the devices are substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date 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 devices, 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 devices are 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 devices 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 devices 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 a legally marketed predicate device 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 (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

510(k) Number: K974636

Application Number:

Device Name: FLOSI (wilofocon A) Rigid Gas Permeable Spherical, Aspherical, Toric, and Bifocal Contact Lenses

Indications for use:

FLOSI (wilofocon A) Rigid Gas Permeable Spherical, Aspherical, Toric, and Bifocal Contact Lenses are indicated for daily wear correction of refractive ametropia (myopia, hyperopia, astigmatism and presbyopia) in aphakic and non-aphakic persons with non-diseased eyes. The lens may be disinfected using a chemical disinfection system only.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Ophthalmic Devices
510(k) Number K974636

Prescription Use ✓ OR Over-The-Counter Use ____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)