AUG 2 4 2001

Reference 510 K number K011072 K011072

PREMARKET NOTIFICATION 510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

1. General Information

Device Trade names: **Gelflex Triton HW (methafilcon A) Translating Bifocal Soft Contact lens**

Gelflex Triton (polymacon) Translating Bifocal Soft Contact Lens

Applicant's Name & Address: **Gelflex Laboratories**
3 Hutton Street
Osborne Park
Perth
Western Australia 6017

The claim is made that the above devices are substantially equivalent to the legally marketed device reference K983912 Vistakon (lenefilcon A) Soft (hydrophilic) Contact Lens approved January 26 1999. We consider that the devices have the same intended use as the predicate device and has different technological characteristics, but these do not raise new questions of safety and effectiveness, and we can demonstrate that the device is as safe and as effective as the legally marketed device.

Indications for use:

The Gelflex Triton HW (methafilcon A) Translating Bifocal Soft Contact Lens is indicated for daily wear for the correction of distance and near vision in presbyopic aphakic and non-aphakic persons with non- diseased eyes. The lens may be worn by persons who have astigmatism of 0.50 diopter or less which does not interfere with visual acuity.

The Gelflex Toric Triton HW (methafilcon A) Translating Bifocal Soft Contact Lens is indicated for daily wear for the correction of distance and near vision in presbyopic aphakic and non-aphakic persons with non- diseased eyes. The lens may be worn by persons who have astigmatism of up to 6.00 diopters. The lenses may be disinfected using a chemical (Not Heat) disinfection system as recommended by your eye care practitioner.

The Gelflex Triton (polymacon) Translating Bifocal Soft Contact Lens is indicated for daily wear for the correction of distance and near vision in presbyopic aphakic and non-aphakic persons with non- diseased eyes. The lens may be worn by persons who have astigmatism of 0.50 diopter or less which does not interfere with visual acuity.

The Gelflex Toric Triton (polymacon) Translating Bifocal Soft Contact Lens is indicated for daily wear for the correction of distance and near vision in presbyopic aphakic and non-aphakic persons with non- diseased eyes. The lens may be worn by persons who have astigmatism of up to 6.00 diopters.

The lenses may only be prescribed for daily wear and must be cleaned and disinfected as recommended by the eye care practitioner. The Gelflex Triton HW (methafilcon A) and Gelflex Toric Triton HW (methafilcon A) Translating Bifocal Soft Contact Lenses may be disinfected using chemical or hydrogen peroxide disinfection systems as recommended by your eye care practitioner. The Gelflex Triton (polymacon) and Gelflex Toric Triton (polymacon) Translating Bifocal Soft Contact Lenses may be disinfected using heat, chemical or hydrogen peroxide disinfection systems as recommended by your eye care practitioner.

2. **Contraindications**

Do not use the GELFLEX TRITON HW Translating Bifocal Soft Contact Lens, Spherical and Toric, Clear or with a Blue Visitint or The GELFLEX TRITON Translating Bifocal Soft Contact Lens Spherical and Toric, Clear or with Blue visitint when any of the following conditions exist:

Acute and subacute inflammation or infection of the anterior chamber of the eye.
Any eye disease, injury, or abnormality that affects the cornea, conjunctiva, or eyelids.
Severe insufficiency of lacrimal secretion (dry eyes).
Corneal hypaesthesia (reduced corneal sensitivity), if not-aphakic.

Any systemic disease that may affect the eye or be exaggerated by wearing contact lenses.

Allergic reactions of ocular surfaces or adnexa that may be induced or exaggerated by wearing contact lenses or use of contact lens solutions.

Allergy to any ingredient, such as mercury or Thimerosal, in a solution which is to be used to care for the GELFLEX TRITON HW Translating Bifocal Soft Contact Lens, Spherical and Toric, Clear or with a Blue Visitint' and GELFLEX TRITON Translating BIFOCAL Soft Contact Lens Spherical and Toric, Clear or with Blue visitint

Any active corneal infection (bacterial, fungal, or viral)

If eyes become red or irritated.

3. **Warnings & Precautions**

The warnings and precautions can be found in the Gelflex Triton HW (methafilcon A) Translating Soft Bifocal Contact Lens and the Gelflex Triton (polymacon) Translating Soft Bifocal Contact Lens labelling.

4. **Solution Compatibility Studies**

Please refer to previous 510K numbers K943178 & K940848

5. **Summary of Clinical Studies:**

Objective

The objective of the trial was to evaluate the safety and effectiveness of the device using existing presbyopic soft contact lens wearers

Study Design

This clinical trial was a prospective, randomised, controlled, multi-centre clinical trial lasting one month.

A total of 60 subjects were enrolled at 5 investigative centres throughout Australia.
30 subjects were fitted with the Gelflex Triton HW (methafilcon A) Translating Bifocal Contact Lens and 30 subjects were fitted with the Gelflex Triton (polymacon) Translating Bifocal Contact Lens.
All enrolled subjects were presbyopes and were existing wearers of contact lenses. The subjects had all been fitted with other available bifocal soft lenses or had been fitted with monovision. All subjects were dispensed with at least one pair of lenses.

There were two lens material types used in this trial, polymacon and methafilcon A, both of which are being marketed for daily wear for single and toric visual corrections. The lenses were worn on a daily basis.
All subjects used the Opti-Free Multipurpose Solution as the lens care regimen on a daily basis. No patients used heat disinfection as this was strongly discouraged and not recommended.

Follow-up visits were to be scheduled at 1 day, week 1, week 2 and week 4.

Primary safety data collected during the study included:

- Adverse events
- Subjective symptoms and problems
- Visual acuity

Primary efficacy data collected during the study included:

- Lens wearing time
- Discontinuations
- Lens replacements & changes

Subjects were eligible for study participation if they were presbyopic.

Demographic Data

The study population consisted of presbyopic subjects representative of the general population attending the Optometrists office for contact lens care.

For the Gelflex Triton (polymacon) Translating Bifocal Contact Lens gender distribution for the enrolled subjects consisted of 8 males and 22 females enrolled into the clinical study and ranged in age from 46 years to 60 years.

For the Gelflex Triton HW (methafilcon A) Translating bifocal Contact Lens gender distribution for the enrolled subjects consisted of 5 males and 25 females enrolled into the clinical study and ranged in age from 46 years to 58 years.

Data Analysis and Results

Adverse Reactions

Adverse reactions were defined as including, but not limited to a hazardous, sight threatening condition such as: corneal ulcer, iritis, other ocular infections, inflammations, corneal scarring, or permanent loss of vision.

There were no adverse reactions.

Symptoms/Problems/Complaints

There were 18 patients who reported initial awareness of the lens. This awareness was related to lens comfort. Patients adapted to the awareness of the lens within one week.

12 patients reported visual interference of the reading portion of the lens with distance viewing. This problem was resolved by reducing the height of the lower segmented portion of the lens. The segment was lowered from 1mm below centre to 1.5mm below the centre of the lens.

Visual Acuity

The results for the Gelflex Triton (polymacon) Translating Bifocal Contact Lens - Visual acuity were reported initially and at each follow-up visit for all subjects.

At the final visit 93% of the group had distance visual acuity of 20/20 or better and 7% had 20/30 or better.

For the reading visual acuity 70% achieved 20/25 or better, 20% achieved 20/30 or better, 6% achieved 20/40 or better and 4% achieved 20/50 or better.

Of the total of 60 lenses (30 subjects) prescribed the breakdown of powers were as follows:

Plus Spheres	37%
Plus Toric	29%
Minus Toric	34%

The results for the Gelflex Triton HW (methafilcon A) Translating Bifocal Contact Lens - Visual acuity were reported initially and at each follow-up visit for all subjects.

At the final visit 92% of the group had distance visual acuity of 20/20 or better and 8% had 20/30 or better.

For the reading visual acuity 66% achieved 20/25 or better, 22% achieved 20/30 or better, 6% achieved 20/40 or better and 6% achieved 20/50 or better.

Of the total of the 60 (30 subjects) lenses prescribed the breakdown of powers were as follows:

Plus Spheres	10%
Plus Toric	18%
Minus Spheres	28%
Minus Toric	44%

Wearing Time

All lenses were worn on a daily wear basis only.

Discontinued Patients

Gelflex Triton (polymacon) Translating Bifocal Soft Contact Lens had 2 subjects discontinue with the wearing of the lens through discomfort.

Gelflex Triton HW (methafilcon A) Translating Bifocal Soft Contact Lens had 0 subjects discontinue with the wearing of the lens.

Lens Replacements and changes

Gelflex Triton (polymacon) Translating Soft Bifocal Lens
Total 60 eyes fitted

Power change distance	22	(15%)
Power change Reading	10	(12%)
Increase Prism for stabilisation	8	(13%)
Steepen Base Curve	9	(15%)
Raise segment height	6	(10%)

Gelflex Triton HW (methafilcon A) Translating Soft Bifocal Lens
Total 60 eyes fitted

Power change distance	4	(6.6%)
Power change Reading	0	
Increase Prism for stabilisation	7	(11.6%)
Steepen Base Curve	2	(3.3%)
Raise segment height	4	(6.6%)

7. Conclusions Drawn from Study

The results of the clinical studies provide assurance of the safety and effectiveness of the Gelflex Triton (polymacon) Translating Bifocal Contact Lens and the Gelflex Triton HW) methafilcon) Translating Bifocal Contact Lens for the patient population, refractive conditions and specified duration of wear.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 2 4 2001

Mr. Peter G. Bryant
General Manager
Gelflex laboratories
3 Hutton Street Osborne Park
Perth Western, Australia 6017

Re: 510(K) Number: K011072
Trade/Device Name: Gelflex Triton (polymacon) and Gelflex Triton HW (methafilcon A) Translating Bifocal Soft Contact Lenses (Spherical and Toric; Clear and Tinted)
Regulation Number: 21 CFR 886.5925
Regulatory Class: Class II
Product Code: LPL
Dated: June 29, 2001
Received: July 2, 2001

Dear Mr. Bryant:

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) 594-6413. 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" (21CFR 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/dsma/dsmamain.html".

Sincerely yours,

A. Ralph Rosenthal

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

510(K) Number: K011072

Device name: Gelflex Triton HW (methafilcon A) Translating Bifocal Soft Contact Lens
Gelflex Triton (polymacon) Translating Bifocal Soft Contact Lens

Indications for Use

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The Gelflex Triton (polymacon) Translating Bifocal Soft Contact Lens is indicated for daily wear for the correction of distance and near vision in presbyopic aphakic and non-aphakic persons with non- diseased eyes. The lens may be worn by persons who have astigmatism of 0.50 diopter or less which does not interfere with visual acuity.

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Ph.D

(Division Sign-Off)
Division of Ophthalmic Devices
510(k) Number K011072

Prescription Use X
(Per 21 CFR 801.109)