K973697

APR - 8 1998

SUMMARY OF SAFETY AND EFFECTIVENESS
K973697

CONTEX (siflufocon A)
RIGID GAS PERMEABLE OK™ (ORTHOKERATOLOGY) CONTACT LENS

1. Submitted by : Contex, Inc.
4505 Van Nuys Blvd.
Sherman Oaks, CA 91403

Contact : NICK STOYAN, PRESIDENT
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Date prepared: March 17, 1998

2. Device:

Common Name: CONTEX OK™ (orthokeratology) contact lens
Trade Name: CONTEX (siflufocon A) Rigid Gas Permeable OK™ (orthokeratology) Contact Lens

Classification Class II (Performance Standards)
21 CFR 886.5916
Rigid gas permeable contact lens

3. Substantial equivalence

A claim of substantial equivalence is based on preamendment status in which a predicate lens of rigid contact lens material was labeled, promoted and distributed in interstate commerce for the same intended use before May 28, 1976.

4. Device description

The CONTEX OK™ (orthokeratology) contact lens is a rigid gas permeable contact lens in a reverse geometry design. The lens material, siflufocon A, is a fluoro silicone acrylate polymer which contains D & C Green #6 as a color additive. The CONTEX OK™ (orthokeratology) contact lens has the following dimensions:

Chord Diameter.....Approximately 6.5 to 13.0 mm
Center Thickness
for Low Minus Lens.....0.10 to 0.30 mm
for Plus Lens: .....0.20 to 0.70 mm
Base Curve .....6.50 to 11.00 mm
Secondary Curves..... 0.1 to 2 mm. Flatter or Steeper than Base Curve
Peripheral Curves..... 0.1 to 2 mm. Flatter or Steeper than Base Curve
Powers .....—10.00 to +5.00 Diopters

Aspheric Lens Eccentricity.....-1.5 to 1.5
(Oblate, Prolate or Tangent Conic)

The physical properties of the lens are:

Refractive Index.....	1.43 (Nd at 25°)
Light Transmittance...	> 92.5% (370-760 nm)
Wetting Angle ... (Contact Receding Angle)	24.0
Specific Gravity....	1.25
Hardness....	82
Water Content...	<1%
Oxygen Permeability..... (cm^2/sec) (ml 0_2 x Hg)	81 x10^{-11}Dk at 35°C

CONTEX OK™ (orthokeratology) contact lenses produce a temporary reduction of myopia by changing the shape (flattening) of the cornea, which is elastic in nature. Flattening the cornea reduces the focusing power of the eye, and if the amount of corneal flattening is properly controlled, it is possible to bring the eye into correct focus and compensate for myopia. Contact lenses rest directly on the corneal tear layer and can influence the corneal shape. After the contact lens is removed, the cornea retains its altered shape for part or all of the remainder of the day. A retainer lens must be used each day to maintain the corneal flattening, or the myopia will revert back to the pre-treatment level.

5. Intended Use

CONTEX (siflufocon A) Rigid Gas Permeable OK™ (orthokeratology) contact lenses are indicated for use in the reduction of myopic refractive error in non-diseased eyes. The lens is indicated for daily wear in an orthokeratology fitting program for the temporary reduction of myopia of up to 3.00 diopters. The lens may be disinfected using a chemical disinfection system only. Note: To maintain the orthokeratology effect of myopia reduction lens wear must be continued on a prescribed wearing schedule.

6a. CONTEX OK™ (orthokeratology) contact lenses have the same technological characteristics as the predicate device, which is designed to purposely flatten the shape of the cornea by applying slight pressure to the center of the cornea. If the cornea is flattened this reduces the focusing power of the eye, and if the amount of corneal flattening is sufficient, it is possible to bring the eye into correct focus and compensate for myopia.

6b1. Preclinical Studies: Described in the original 510 (k) submission K941883

6b2. Clinical Studies

A total of 138 eyes were enrolled in this investigation and accounted for, with 136 eyes dispensed contact lenses. A total of 110 eyes completed a minimum of three months

of contact lens wear, 12 eyes were incomplete and 16 eyes were discontinued. A large portion of the patients in this study (49.1%) had previous contact lens wearing experience, with the remainder consisting of new wearers.

ADVERSE REACTIONS

There were no eyes that experienced adverse reactions, slit lamp finidngs requiring treatment or symptoms, problems and complaints requiring treatment.

SLIT-LAMP FINDINGS

There were a total of 188 reports of grade 1 slit-lamp findings during the three-month course of this study including 6 for edema, 108 for staining, 24 for injection, and 50 for tarsal abnormality. There were no reports of slit-lamp findings of Grade 2 or higher. There were no reports of any slit lamp findings for Vascularization or Other conditions. The total number of slit-lamp findings was within expected limits for an RGP contact lens. The large number of reports for Tarsal Abnormalities can be attributed to the group of soft lens wearers that entered the study. All finding reduced in incidence over time.

SYMPTOMS, PROBLEMS, AND COMPLAINTS

There were a total of 425 reports of symptoms, problems or complaints during the three-month course of this study. The largest number of complaints (20.2%) was for blur following lens wear. This occurred because very often the lens caused some corneal flattening but it was not sufficient to correct for the patient's refractive error. The next largest number of complaints (17.2%) was for Variable Vision, which occurred because of corneal changes after lens removal. The high incidence of symptoms related to blur following lens wear can be attributed to the expected condition for orthokeratology, especially in the early wearing period, when the cornea is undergoing change. Other complaints were consistent with those found generally for wearers of RGP contact lenses.

KERATOMETRY

Most eye meridians (89%) flattened during the three-month period of this study. The average flattening was 1.17 diopters and the greatest flattening was 4.13 diopters. Of the 110 eyes (55 patients) which completed the three month clinical, 8% showed no change in corneal astigmatism, 32% showed a decrease less than one diopter, while 41% showed an increase less than one diopter and 16% showed an increase greater than one diopter.

It has been pointed out in several studies of keratometry that the change in corneal flattening from orthokeratology, as measured in keratometer diopters, is generally less than the change in refractive power which results in a reduction in myopia. This is generally attributed to keratometer error due to the separation of the mires being outside of the central corneal area.

REFRACTIVE POWER

A total of 106 eyes showed some reduction in myopic refractive error during the 3-month time period that the CONTEX OK™ (orthokeratology) contact lenses were worn. The average reduction was 1.69 diopters with a range from 0.25 to 4.25 diopters. This included 35

eyes (32%) with a reduction of between 0.25 and 1.00 D., 35 eyes (32%) between 1.25 and 2.00 D., 25 eyes (23%) between 2.25 and 3.00 D., 10 eyes (9%) between 3.25 and 4.00 D. and one eye (1%) reduced by 4.25 D. One eye had no change and 3 eyes increased in minus power by 0.25 D. The average reduction in refractive power was 1.69 and the median was 1.63. The reduction in myopia was greater for eyes with a higher initial refractive error. No eyes over -3.50 diopters were able to achieve a full reduction in myopia. For eyes with an initial myopia of greater than 3.75 diopters the average final exam reduction in myopia was 2.75 diopters. The limit in initial myopia that could be reduced to emmetropia in some eyes was -3.50 diopters.

The average amount of myopia reduction is shown in the following table:

AVERAGE REDUCTION IN MYOPIA (M)

INITIAL Myopia	REDUCTION Myopia
-1.00	0.80
-2.00	1.50
-3.00	2.00
-4.00	2.40

There was an insignificant difference between the patients who wore contact lenses prior to the study and those with no previous contact lens experience. The percentage of patients that achieved full or partial temporary refractive reduction is shown in the following table.

PERCENT OF EYES THAT ACHIEVED FULL OR PARTIAL TEMPORARY REDUCTION OF MYOPIA

INITIAL MYOPIA	FULL TEMPORARY REDUCTION	UP TO 0.50 D. UNDER FULL REDUCTION	FINAL V.A. 20/20 or better	FINAL V.A. 20/40 or better
≤1.00 D	52%	84%	78%	100%
-1.25 to - 2.00 D.	36%	55%	74%	96%
-2.25 to - 3.00 D.	18%	35%	48%	72%
-3.25 to - 4.00 D.	4%	13%	16%	64%

VISUAL ACUITY

For the patients (110 eyes) that completed this study, the initial visual acuity by best refraction was 20/20 or better for 104 eyes and 20/40 or better for all eyes (110). At the final visit, visual acuity with contact lenses was equal to or better than 20/20 for 99 eyes, 20/40 for 109 eyes and one eye had a visual acuity of 20/70. Nine eyes had a one-line drop in visual acuity for contact lenses compared to best refraction, one eye had a two-line drop and three eyes had a three-line drop. In each case the reduced visual acuity was attributed to residual astigmatism when wearing contact lenses.

The percentage of eyes that achieved uncorrected visual acuity of 20/20 or better and 20/40 or better in relation to the initial myopia is given in the above table. A total of 43 (39%) eyes achieved a visual acuity of 20/20 or better and 78 (71%) eyes achieved 20/40 or better. The study did not report how long improved vision lasted after lenses were removed.

WEARING TIME

The average wearing time required for patients who wore CONTEX OK™ (orthokeratology) contact lenses for various time periods was as follows:

One week	7.7 hours
Two weeks	7.8 hours
One month	8.0 hours
Three months	8.4 hours

There was considerable variability, however, as many patients required several hours more or less than the averages as shown for the three-month time period as follows:

Time Worn	Percent of patients
0 to 4 hours	25.5%
4.1 to 8 hours	21.8%
8.1 to 12 hours	23.7%
12.1 to 16 hours	27.2%

LENS REPLACEMENTS

A total of 217 lenses were replaced over the three-month period of this study. The largest number of replacements were for visual acuity (62) and base curve (142). This is a larger number of lenses replaced than would be expected for a regular RGP lens, but not for the orthokeratology lens of this study. A large number of lens replacements is expected to achieve the desired fitting relationship with the lens base curve as the cornea flattens.

6b3. Safety and Effectiveness

The device is safe as demonstrated by the minimal incidence of signs and symptoms and the lack of any adverse reactions during the course of the clinical studies.

The device is effective as demonstrated by the temporary improvement in visual acuity and reduction in myopia as claimed.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR - 8 1998

Nick Stoyan
President
CONTEX, INC.
4505 Van Nuys Blvd.
Sherman Oaks, CA 91403

Re: K973697
Trade Name: CONTEX OK ™ (siflufocon A) Rigid Gas Permaeble Contact Lens for Orthokeratology
Regulatory Class: II
Product Code: 86 HQD
Dated: March 9, 1998
Received: March 10, 1998

Dear Mr. Stoyan:

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) 594-4613. 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" (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 (if known): K973697

Device Name: CONTEX OK™ (siflufocon A) Rigid Gas Permaeble Contact Lens for Orthokeratology

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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)

(Division Sign-Off)
Division of Ophthalmic Devices
510(k) Number K973697

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

(Optional Format 1-2-96)