SUMMARY OF SAFETY AND EFFECTIVENESS DATA

I. GENERAL INFORMATION

Device Generic Name: tisilfocon A rigid gas permeable contact lenses

Device Trade Name: Paragon-Z CRT® (tisilfocon A) Rigid Gas Permeable Contact Lenses for Corneal Refractive Therapy

Applicant's Name and Address: Paragon Vision Sciences
947 East Impala Avenue
Mesa, AZ 85204-6619

Date of Panel Recommendation: None

Premarket Approval Application (PMA) Number: P050031

Date of Notice of Approval to Applicant: November 16, 2006

II. INDICATIONS FOR USE

The Paragon-Z CRT® (tisilfocon A) Rigid Gas Permeable Contact Lenses for Corneal Refractive Therapy are indicated for use in the reduction of myopic refractive error in non-diseased eyes. The lenses are indicated for overnight wear in a Contact Lens Corneal Refractive Therapy fitting program for the temporary reduction of myopia up to 6.00 diopters in eyes with astigmatism up to 1.75 diopters. The lenses may be disinfected using only a chemical disinfection system.

Note: To maintain the Contact Lens Corneal Refractive Therapy effect of myopia reduction, overnight lens wear must be continued on a prescribed schedule. Failure to do so can affect daily activities (e.g., night driving), visual fluctuations and changes in intended correction.

III. CONTRAINDICATIONS

Paragon-Z CRT® contact lenses for Corneal Refractive Therapy should not be used when any of the following conditions exist:

- Acute and subacute inflammations or infection of the anterior segment of the eye.
- Any eye disease, injury, or abnormality that affects the cornea, conjunctiva, or eyelids.

- Severe insufficiency of tears (dry eyes).
- Corneal hypoesthesia (reduced corneal sensitivity).
- Any systemic disease that may affect the eye or be exacerbated by wearing contact lenses.
- Allergic reactions of ocular surfaces or adnexa which 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 contact lenses.
- Any active corneal infection (bacterial, fungal or viral).
- If eyes become red or irritated.

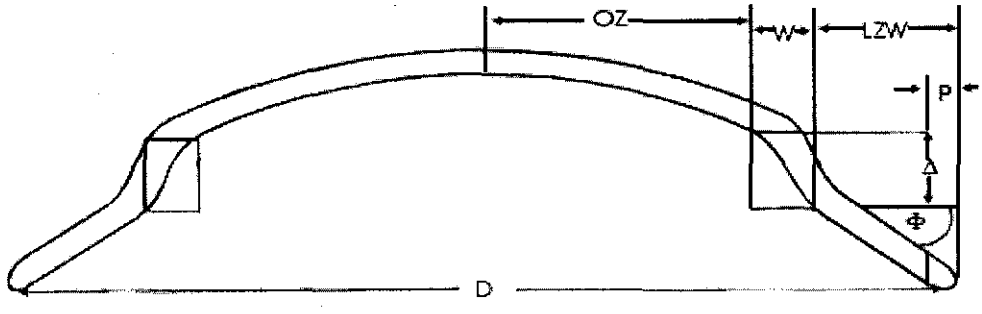
IV. WARNINGS AND PRECAUTIONS

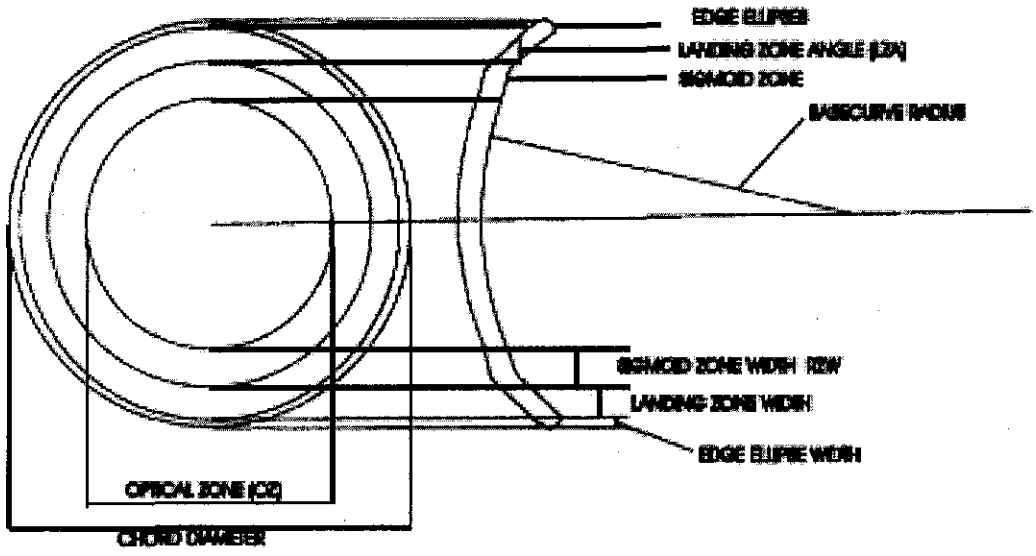
The warnings and precautions can be found in the device labeling (Attached).

V. DEVICE DESCRIPTION

Paragon-Z CRT® (Sigmoid Proximity Control Design)

Paragon- Z CRT® contact lenses are manufactured from Menicon Z™ material (tisilfocon A). The lenses are designed to have congruent anterior and posterior surfaces each consisting of three zones:





1. The central spherical zone (OZ).

2. A mathematically designed sigmoid corneal proximity "Return Zone" (W).

3. A non-curving "Landing Zone" (LZW).

The lens design also includes a convex elliptical edge terminus smoothly joining the anterior and posterior surfaces.

Paragon-Z CRT® lenses for contact lens corneal refractive therapy are to be worn overnight with removal during all or part of each following day. The lens material (tisilfocon A) is a thermoset copolymer derived from fluoromethacrylate and siloxanylstyrene, bound by crosslinking agents. The lenses for corneal refractive therapy are available as lathe-cut contact lenses with a light blue tint. The blue tinted lens contains D & C Green No. 6. Also, a UV absorber (Benzotriazol) is added during the manufacturing process.

VI. ALTERNATIVE PRACTICES OR PROCEDURES

The alternative practices and procedures to correcting myopia by wearing these lenses include wearing daily wear rigid gas permeable (RGP) lenses in a reverse geometry design, wearing traditional daily or extended wear RGP or soft (hydrophilic) contact lenses, wearing spectacles, and refractive surgeries such as LASIK.

VII. MARKETING HISTORY

The Paragon-Z CRT® (tisilfocon A) lens has not been previously marketed.

VIII. POTENTIAL ADVERSE EFFECTS OF THE DEVICE ON HEALTH

Potential adverse effects on health associated with contact lenses worn overnight include eye problems such as corneal ulcers, epithelial microcysts, infiltrates and endothelial polymegathism.

The risk of corneal ulcer has been shown to be greater among users of overnight wear contact lenses than among users of daily wear contact lenses. The risk among overnight wear users increases with wear time. In addition, smoking increases the risk of corneal ulcers for contact lens users, especially when lenses are worn overnight or while sleeping. Strict compliance with the proper lens care regimen and wearing schedule is essential in minimizing risk.

IX. SUMMARY OF PRECLINICAL STUDIES

The application includes by reference the preclinical tests and results in the approved original PMA, P990018 for the Menicon Z™ (tisilfocon A) contact lens, which is made of the same lens material. The application also includes by reference P870024/S043 for Paragon CRT™ (paflufocon B) and CRT 100™ (paflufocon D) contact lenses which are of the same lens design and lathe manufacturing.

X. SUMMARY OF CLINICAL STUDIES

A. Objective

The objective of this investigation was to assess the safety and effectiveness of the Paragon Z CRT® corneal refractive therapy lenses worn overnight to treat myopia.

B. Study Design

This was a prospective, non-randomized study involving nine clinical centers. One hundred two subjects (two hundred four eyes) were enrolled. The study included both adults and adolescents ≥ 12 years. Subjects were followed for 6 months, with visits at 1 day, 2 weeks, and 1, 2, 3 and 6 months after lenses were dispensed. Additional visits were conducted at 8, 24, 48 and 72 hours after the 3 or the 6 month visit to determine the unaided visual acuity improvement duration on at least a single eye of each subject.

The endpoints used to evaluate the safety of the treatment are:

- The proportion of eyes with a loss of two or more lines of BSCVA.
- The proportion of eyes with a post-treatment BSCVA of worse than 20/40.
- The proportion of eyes with adverse events.
- The proportion of eyes with slit lamp findings greater than level 2 at any follow-up visit.

- The proportion of eyes with symptoms, problems and complaints at each follow-up visit.

The endpoints used to evaluate the effectiveness of the treatment are:

- The proportion of eyes that achieve uncorrected visual acuity (UCVA) of 20/20 or better and 20/40 or better.
- The proportion of eyes that have a reduction in manifest refraction spherical equivalent (MRSE) at six months of treatment
- The proportion of eyes that achieve predictability (attempted versus achieved) of the manifest refraction spherical equivalent of within ± 0.50 D and ± 1.00 D.
- The proportion of eyes that achieve stability of MRSE as defined by a change of no more than 0.50 D and no more than 1.00 D between two consecutive visits at least 2 months apart.
- The proportion of eyes that have a reduction of corneal curvature and absolute corneal astigmatism at six months of treatment.

C. Demographic Information

The data presented in this clinical study summary were collected and analyzed from 204 eyes of 102 enrolled subjects, of which 196 eyes of 98 subjects were treated. The mean age of the full cohort of patients was 34.56 ± 11.6 years (range 11 to 57). There were 10 adolescent subjects enrolled, 2 withdrew prior to treatment. There were 67 female and 31 male subjects treated.

The data for 72 patients (144 eyes) were analyzed for effectiveness following 6 months of treatment. The mean age of these patients was 34.97 ± 12.0 years (range 11 to 57). A waiver was granted for one subject that was age 11 years 8 months at the baseline visit. There were 48 female and 24 male subjects; of these 47 were Caucasian, 3 were African American, 14 were Asian/Pacific Islander, 1 was American Indian/Aleut Eskimo, and 5 were Hispanic.

D. Accountability

One hundred two subjects underwent baseline evaluation in the study. Of these, 98 subjects (196 eyes) had lenses dispensed and wore them for at least one night of treatment. The safety analysis was conducted on all 196 treated eyes of the 98 subjects.

Seventy-two subjects, 73.5% (144/196 eyes), completed six months of treatment. (At one month one subject converted to and completed the study wearing only 1 lens.) The efficacy analysis was conducted on all 72 subjects (144 eyes) that completed six months of treatment.

Twenty nine subjects were discontinued prior to the six-month visit.

The clinical reasons for discontinuation are unacceptable vision, lack of comfort, lens adherence and lens slipping that account for 13 % (13/98), 3 % (3/98), 2% (2/98) and 1% (1/98) respectively. The total discontinuation rate for clinical reasons was 19 %.

E. Data Analysis and Results

EFFECTIVENESS OUTCOMES

Average Reduction in Myopia

The average amount of myopia that can be expected to be corrected is shown in Table 1. These values, assessed on 137 eyes on which full correction was attempted, are only averages and some patients can be expected to achieve more or less than these averages.

Table 1
AVERAGE REDUCTION IN MYOPIA (DIOPTERS) N=137*

Refractive Range and Count	Average Subjective Refraction (MRSE)	Average Myopia Reduction (MRSE)	Average Residual Subjective Refraction (MRSE)
-0.25>-1.00 N=8	-0.89	0.81+/ -0.48	-0.08+/ -0.38
-1.25>-2.00 N=40	-1.63	1.49+/ -0.45	-0.13+/ -0.40
-2.25>-3.00 N=46	-2.57	2.37+/ -0.62	-0.20+/ -0.57
-3.25>-4.00 N=25	-3.67	3.23+/ -0.67	-0.44+/ -0.62
-4.25>-5.00 N=13	-4.40	3.88+/ -0.67	-0.52+/ -0.60
-5.25>-6.00 N=5	-5.50	5.65+/ -0.55	0.15+/ -0.55

*All completed eyes targeted for emmetropia.

Uncorrected Visual Acuity (UCVA)

Post treatment visual acuity was assessed on 137 eyes on whom full correction was attempted. Of these eyes 41.5% obtained 20/20 or better uncorrected visual acuity and 94.8% obtained 20/40 or better visual acuity at 6 months (Table 2).

Paragon Z CRT® Contact Lenses for Corneal Refractive Therapy provided a temporary full reduction in some patients with up to -5.5 diopters of myopia. For patients with greater than -5.5 diopters of myopia only a partial reduction of myopia can be expected. The percentage of patients that can be expected to achieve full or partial temporary refractive reduction based on 144 [1] treated eyes is also shown in Table 2.

[1] At 1 month one subject converted to, and completed wearing only one lens.

Table 2

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

INITIAL MYOPIA	FULL REDUCTION ± 0.50 D from Target*	PARTIAL REDUCTION ± 1.00 D from Target*	FINAL V.A 20/20 or better**	FINAL V.A 20/40 or better**
1.00 D or less	88%	N/A	50%	100%
-1.25 to - 2.00 D	83%	100%	60%	95%
-2.25 to - 3.00 D	81%	95%	39%	93%
-3.25 to - 4.00 D	70%	93%	24%	92%
-4.25 to - 5.00 D	79%	86%	23%	100%
-5.25 to -6.00 D	33%	83%	33%	100%

* N=144 for reduction (all efficacy qualified eyes)

** N=137 for Final VA (only eyes targeted for emmetropia)

Accuracy

Accuracy of outcome was evaluated by analysis of attempted versus achieved manifest refraction spherical equivalent. At the 6 month visit, 77.6% (111/144 [2]) of 6-month completed eyes were within 0.50 D attempted spherical equivalent correction, and 95.1% (136/144) of eyes were within 1.00 D of attempted correction. In this clinical study the higher the initial myopia, the lower the percentage of patients that achieved full correction and/or 20/20 vision. The preceding table demonstrates the relationship of initial myopia with treatment success.

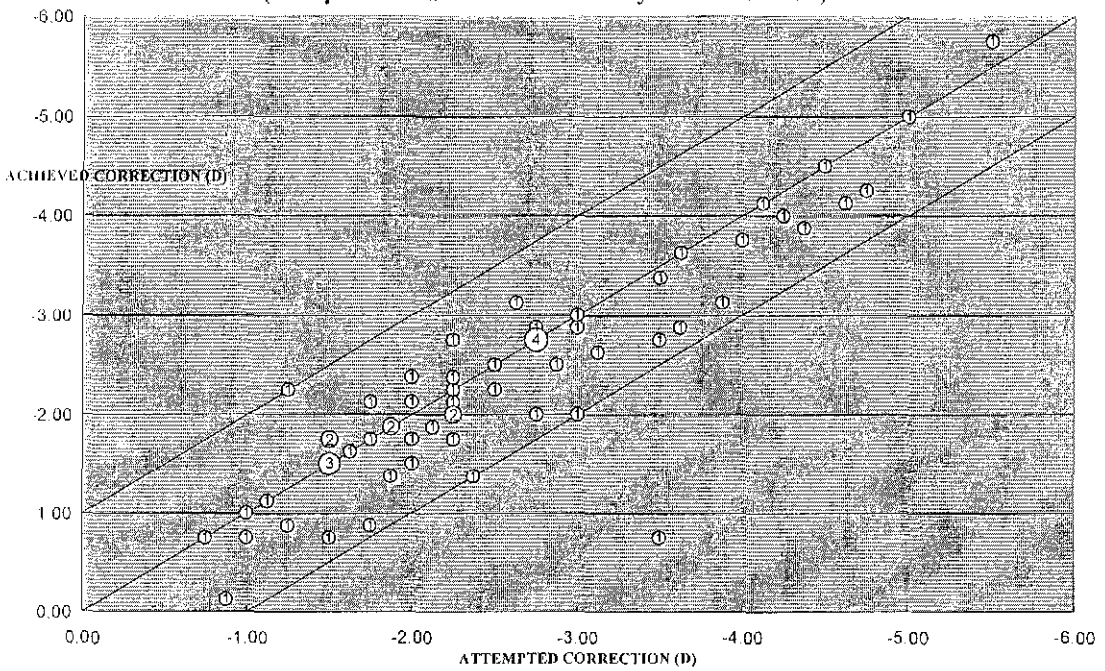
There is reference in a published study [3] regarding visual acuity in the "better seeing eye" of a subject as a useful method of estimating functional vision when using both eyes. When the study subjects were analyzed for only their "better seeing eye", 86% had 20/20 or better vision, and 100% had 20/40 or better. Eighty percent are estimated to be within 0.5 D of target and 96% are estimated to be within 1.0 D of target with the method of better eye analysis. The scatter plot (Figure 1) below graphically depicts the accuracy of the treatment based on the better seeing eye.

[2] At 1 month one subject converted to, and completed wearing only one lens.

[3] Monocular Versus Binocular Visual Acuity as Measures of Vision Impairment and Predictors of Visual Disability, Rubin, et al, Invest Ophthalmol Vis Sci 2000; 41:3327-3334

Figure 1

ATTEMPTED versus ACHIEVED Correction of Refractive Error
Estimated From The Residual Error Of the Better Seeing Eye, N=65*
(multiple identical results indicated by number in circle)



* Excludes 7 subjects not targeted for emmetropia in both eyes.

Wearing Time

The lenses were used for overnight wear only. They were applied within 30 minutes of sleep and removed within 30 minutes of awakening. The average wearing time was 6 to 8 hours and reflected the expected distribution of night sleep time. There was no apparent relationship between the number of hours of wear during sleep and the visual acuity outcome for any amount of pretreatment myopia.

Regression Of Visual Acuity

To assess the change over time following lens removal, subjects in the clinical study were evaluated at 8, 24, 48, and 72 hours after removal of their lenses following either the three or six month scheduled visit. The 1 diopter regression point was chosen because it approximately corresponds to 20/40 unaided vision, the legal requirement for driving in many states.

Values in Table 3 represent the number of hours from the time of lens removal before the average patient's vision will have regressed to the point that his refraction is -1.0 diopters.

Table 3
AVERAGE AND MINIMUM HOURS UNTIL REGRESSION TO -1.0 DIOPTER OR WORSE
(estimated for all subjects with pretreatment MRSE ≥ -1.0 D targeted for emmetropia and corrected to better than -1.0 D MRSE N=79)

REFRACTION AT LENS REMOVAL			-1.12 to -2.00	-2.12 to -3.00	-3.12 to -4.00	-4.12 to -5.00	-5.12 to -6.00
	+0.50	**Mean**	**163.7 Hrs**	**52.6 Hrs**	**19.8 Hrs**	**12.1 Hrs**	**16.9 Hrs**
		Minimum	9.3 Hrs	3.7 Hrs	4.3 Hrs	5.3 Hrs	5.5 Hrs
	+0.25	**Mean**	**162.3 Hrs**	**51.6 Hrs**	**18.9 Hrs**	**11.4 Hrs**	**15.9 Hrs**
		Minimum	9.3 Hrs	3.5 Hrs	4.1 Hrs	4.9 Hrs	5.1 Hrs
	0.00	**Mean**	**159.4 Hrs**	**49.9 Hrs**	**17.5 Hrs**	**10.5 Hrs**	**14.4 Hrs**
		Minimum	9.2 Hrs	3.2 Hrs	3.9 Hrs	4.4 Hrs	4.7 Hrs
	-0.25	**Mean**	**153.5 Hrs**	**46.9 Hrs**	**15.5 Hrs**	**9.1 Hrs**	**12.3 Hrs**
		Minimum	9.1 Hrs	2.8 Hrs	3.4 Hrs	3.8 Hrs	4.1 Hrs
	-0.50	**Mean**	**139.7 Hrs**	**41.1 Hrs**	**12.3 Hrs**	**7.1 Hrs**	**9.5 Hrs**
		Minimum	8.5 Hrs	2.2 Hrs	2.8 Hrs	2.9 Hrs	3.1 Hrs
	-0.75	**Mean**	**103.9 Hrs**	**28.8 Hrs**	**7.5 Hrs**	**4.3 Hrs**	**5.5 Hrs**
		Minimum	5.1 Hrs	1.2 Hrs	1.6 Hrs	1.6 Hrs	1.8 Hrs

Effects on Astigmatism

Corneal Refractive Therapy does not predictably affect the magnitude of pretreatment astigmatism. Of the eyes that completed the six month clinical study, 27% showed no change in refractive astigmatism, 49% showed a decrease of one diopter or less and 1% showed a decrease more than one diopter, while 23% showed an increase of one diopter or less and 1% showed an increase greater than one diopter of refractive astigmatism.

SAFETY OUTCOMES

In this trial, 196 eyes from 98 patients were evaluated for safety during six months overnight wear corneal refractive therapy when treating myopia and myopia with astigmatism. Analysis of safety outcomes was performed for best spectacle corrected acuity (BSCVA), slit lamp findings, symptoms and complaints, adverse events and complications, and intraocular pressure. The analysis was completed for all eyes that reported at all visits.

Best Spectacle Corrected Visual Acuity (BSCVA)

The BSCVA change analyzed in this trial is the difference between the baseline acuity with best subjective refraction and the acuity with the subjective refraction at the specified visit.

Seventy percent of completed eyes (101/144 [4]) experienced no change in BSCVA at 6 months, while 15 % (22/144) experienced one line of improved BSCVA and 10% (14/144) eyes experienced one line of diminished BSCVA. Five completed eyes, 3.5% (5/144) manifested a transient loss of two or more lines of BSCVA at the six month visit. All losses except one were found to be transient as they were not found to be present at the post-removal visits. In one case recovery was not documented before the eye was lost to follow-up. There was one eye with BSCVA worse than 20/40 at the six month visit. At prior visits, with the exception of 3 cases, eyes measuring worse than 20/40 BSCVA were retested with a contact lens in place. In those cases retested with a lens, the acuity improved to within one line of vision, indicating that the loss was due to higher order aberration in the anterior corneal plane. In the cases when the test was mistakenly omitted, the BSCVA loss improved to within one line of vision by the next scheduled visit. There is a pattern of transient BSCVA loss at each visit and a trend toward a decreasing percentage with time.

After passing the dispensing and a successful day one visit, 35 eyes were found to have temporarily lost 2 lines of BSCVA from baseline at some time during the study. In one case recovery was not documented before the eye was lost to follow-up. Additionally, eight subjects were observed to temporarily have BSCVAs of 20/40 or worse.

Absence of Persistent Corneal Change

All treated eyes of subjects who discontinued the clinical trial were followed one month post discontinuation and every one month thereafter until there was no difference greater than 0.50 D in either of the keratometric meridians from the baseline measures. Of the 58 discontinued eyes of the 29 discontinued subjects, 39 eyes of 20 subjects were within 0.50 D of the baseline measurements at the discontinuation visit. Eleven eyes of 6 subjects were measured to be within 0.50 D of their baseline visit at a post discontinuation visit. One of the discontinued subjects (2 eyes) was lost to follow-up during the investigation. Two enrolled subjects that discontinued were not dispensed lenses.

Slit Lamp Findings

There were no grade 2 or 3 observations at baseline. There were 1578 observations for all scheduled and unscheduled follow up visits. There were 61 grade 2 (mild) observations (3.9%) during treatment and 7 grade 3 (moderate) observations (< 0.5%) reported. There were no grade 4 (severe) observations reported that would constitute adverse events.

Of the 8 grade 3 reports, 5 were for staining, 1 was for injection and 2 were described as corneal infiltrates. These occurred in 4 subjects. In each case lens wear was

[4] At 1 month one subject converted to, and completed wearing only one lens.

discontinued. Two subjects discontinued the study and 2 completed. All 8 cases resolved without further complication.

Table 4 below summarizes the findings related to these events.

Table 4

Eye	Date	Visit	Treatment for Grade 3 Staining
OD	06/10/04	Two Wk	Discontinued Lens Wear for 6 Days
OS	06/10/04	Two Wk	Discontinued Lens Wear for 6 Days
OD	05/27/04	Day One	Discontinued Lens Wear for 24 Hours
OD	07/15/04	Day One	Not Contact Lens Related - Discontinued Lens Wear for 1 Week
OS	07/15/04	Day One	Not Contact Lens Related - Discontinued Lens Wear for 1 Week

Symptoms and Complaints

Table 5 shows the number and type of symptoms or complaints reported at each scheduled or unscheduled visit. The most commonly reported symptom was discomfort.

Table 5

PERCENT OF EYES EXHIBITING COMPLAINT OR SYMPTOM AT VISIT						
Visit	Unscheduled	2-Week	1-Month	2-Month	3-Month	6-Month
Total Eyes at Visit	260	168	158	164	160	144
None	39%	44%	63%	68%	69%	81%
Discomfort	24%	20%	15%	14%	15%	8%
Itching/Burning	6%	4%	0%	4%	1%	0%
Blurred Vision	26%	20%	8%	4%	4%	5%
Dryness/Scratch	6%	3%	6%	7%	3%	5%
Redness	5%	2%	1%	0%	0%	0%
Variable Vision	12%	15%	4%	2%	4%	3%
Photophobia	3%	1%	0%	0%	1%	0%
Halos	4%	11%	8%	5%	3%	1%
Ghost Images	0%	1%	1%	1%	0%	1%
Lens Adhesion	5%	2%	1%	0%	1%	1%
Lens Need Cleaning	2%	5%	1%	3%	0%	1%
Other	6%	3%	1%	1%	0%	2%

Adverse Events and Complications

There were three adverse events reported. Two were rated as moderate and one was rated as mild.

A peripheral corneal infiltrate reported for one subject who discontinued lens wear and was treated with medication resolved in 7 days. A second subject had two occurrences

18

of corneal infiltrates which resolved in 6 days. This subject also discontinued lens wear and was administered medication.

No serious adverse events were reported.

Lens adherence was reported in two subjects who discontinued and was listed as a study related complication. It was also reported as a symptom, problem or complaint. There were twenty one reports of lens adherence in thirteen eyes of nine subjects. Only one of these eyes had lens adherence at multiple visits (this eye was also reported to have a moderate adverse event as noted above.)

The remaining study related complications were restricted to the transient losses of two or more lines of BSCVA, reductions to $\leq$ 20/40 and to slit lamp findings graded at level 3 (moderate).

For subjects completing at least a day 1 visit there were 63 occurrences in 50 eyes of temporary loss of 2 or more lines of visual acuity (BSCVA). Of 186 subject eyes that continued to scheduled visits beyond day 1, and excluding observations at day 1 visits, there were 35 occurrences of temporary loss of 2 or more lines of visual acuity. Of these occurrences 15 occurred on scheduled visits beyond the early fitting period (dispensing through successful 2 week visit), and 7 were at unscheduled or discontinuation visits. The average time until the investigator was able to examine the subject and document recovery to better than 2 lines from baseline was 31.4 days. Although the range of durations until documented recovery was 0 to 216 days (one subject could not be returned for documentation), the median duration was 18 days.

Of the 15 occurrences beyond the early fitting period, none were bilateral and the average logMAR acuity at the time of the first observation was 0.17 (better than 20/32 in that eye). Only two of these eyes demonstrated visual acuities worse than 20/40 when first observed and they were documented to have been resolved at their next follow-up visits in 7 and 21 days respectively.

Eight subjects presented with acuities (BSCVA) of $\leq$ 20/40 during the course of the study. Two were observed only at the day 1 visit. One subject placed lens cleaner in his eye just after the 3-month visit but was not documented to have recovered until the 6-month visit. Excluding the subject who put cleaner in his eye, the range for time to documented recovery was 0.3 – 21 days with a median of 11 days.

A summary of the key safety variables is presented in Table 6.

Table 6
Summary of Key Safety Variables *

Criteria	1 Day		2 Weeks		1 Month		2 Months		3 Months		6 Months		Unscheduled**	
	n	%	n	%	n	%	n	%	n	%	n	%	n	%
N	196		168		158		164		160		144		210	
Adverse events													3	1.4
Loss of ≥ 2 lines BSCVA***	32††	12.5	9	5.4	4	2.5	2	1.2	4	2.5	5	3.5	7	3.3
BSCVA worse than 20/40 ***	4	1.6	3	1.8	1	0.6	0	0	1	0.6	1	0.7	2	1.0
Increase of > 1 D Refractive Cyl	2	0.8	4	2.4	2	1.3	1	0.6	0	0	0	0	6	2.9
Increase of > 2 D Refractive Cyl †	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Increase of > 1 D Corneal Cyl	16	6.3	8	4.8	5	3.2	7	4.3	12	7.5	10	6.9	12	5.7
Increase of > 2 D Corneal Cyl †	0	0	4	2.4	0	0	2	1.2	3	1.9	1	0.7	0	0

* Includes multiple interim observations of some events.

** Includes Discontinuation visits and regression study visits.

*** There were 35 incidents of loss ≥ 2 lines of vision (all documented to be temporary except one).

† All cylinder increases of ≥ 2 Diopters were temporary.

†† On the 32 day-one observations, 4 of these observations were still observed at the 2-week visit (in addition to the 9 new cases at 2 weeks noted in the table).

Intraocular Pressure (IOP)

Thee were no eyes reported to have increases of IOP of more than 10 mmHg.

Patient Satisfaction

Fifty-nine of the 72 completed subjects (85.3%) rated their overall satisfaction with their unaided vision very good or excellent at the 6 month visit compared to no subjects (0.0%) at pretreatment.

XI. CONCLUSIONS DRAWN FROM THE STUDIES

The preclinical tests referenced provide evidence that the lens material is biocompatible and the device is manufactured according to the design specifications. No serious adverse events were observed during the clinical study and 94.8% of the eyes achieved 20/40 or better visual acuity at 6 months.

The results of the preclinical and clinical studies provide reasonable assurance of the safety and effectiveness of the devices for the study population, refractive conditions and specified wearing modality when used as indicated in accordance with the directions for use.

XII. PANEL RECOMMENDATION

In accordance with the provisions of section 515(c)(2) of the act as amended by the Safe Medical Devices Act of 1990, this PMA was not referred to the Ophthalmic Devices Panel, an FDA advisory committee, for review and recommendation because the information in the PMA substantially duplicates information previously reviewed by this panel.

XIII. CDRH DECISION

During review of this PMA, the risk of microbial keratitis associated with the use of overnight orthokeratology contact lenses in the pediatric (below age 18) population was raised in the published literature. As one of the currently approved PMA overnight orthokeratology manufacturers Paragon Vision Sciences received an order under section 522 of the Federal Food, Drug and Cosmetic Act dated May 25, 2006 to conduct a post market surveillance study of its currently marketed CRT device manufactured in pafluflocon RGP material. The company has agreed to conduct the section 522 study and submit a protocol to address the risk of microbial keratitis in pediatric patients, submit the results of the section 522 study in a post approval report to this PMA, and to include the results of the study in the labeling of this Paragon-Z CRT® device via a supplement to this PMA when the study is completed.

FDA issued an approval order on November 16, 2006.

The applicant's manufacturing facility was inspected and was found to be in compliance with the Quality System Regulation (21 CFR 820).

XIV. APPROVAL SPECIFICATIONS

Directions for use: See the labeling.

Hazards to Health from Use of the Device: See Indications, Contraindications, Warnings, Precautions and Adverse Events in the labeling.

Postapproval Requirements and Restrictions: See approval order.