SUMMARY OF SAFETY AND EFFECTIVENESS DATA (SSED)

I. GENERAL INFORMATION

Device Generic Name: Overnight orthokeratology contact lens

Device Trade Name: Optimum Infinite (tisilfocon A) Orthokeratology Lenses II

Device Procode: NUU

Applicant's Name and Address: Contamac, Ltd.
Carlton House
Shire Hill
Saffron Walden
Essex CB11 3AU
United Kingdom

Date(s) of Panel Recommendation: None

Premarket Approval Application (PMA) Number: P240045

Date of FDA Notice of Approval: February 10, 2026

II. INDICATIONS FOR USE

The Optimum Infinite (tisilfocon A) Orthokeratology Lenses II for overnight wear are indicated for use in the reduction of refractive error in non-diseased eyes. The lenses are indicated for overnight wear for the temporary reduction of myopia up to 6.00 diopters with eyes having astigmatism up to 1.75 diopters. The lenses may only be disinfected using a chemical disinfection system.

Note: To maintain the Orthokeratology 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) and cause visual fluctuations and changes in intended correction.

III. CONTRAINDICATIONS

Optimum Infinite (tisilfocon A) Orthokeratology Lenses II for overnight wear should not be used when any of the following conditions exist:

- Acute and subacute inflammations 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 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 Optimum Infinite (tisilfocon A) Orthokeratology Lenses II labeling.

V. DEVICE DESCRIPTION

Optimum Infinite Orthokeratology Lenses II are manufactured from Optimum Infinite material (tisilfocon A). The lenses are designed to have congruent anterior and posterior surfaces each consisting of three zones:

1. The central spherical zone (BC).
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 (P).

Optimum Infinite Orthokeratology Lenses II 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 are available as lathe-cut contact lenses with a blue, green, red or yellow tint. The blue tinted lens contains D&C Green #6. The green tinted lens contains D&C Green #6 and D&C Yellow #18. The red tinted lens contains D&C Red #17 and D&C Yellow #18. The yellow tinted lens contains D&C Yellow #18. Also, a UV absorber (Benzophenone type) is added during the manufacturing process. The lens surface may be oxygen plasma treated.

Solutions used for wet shipping are listed below:

1. Boston SIMPLUS solution cleared under K024289
2. Menicon Unique pH solution cleared under K130805

The lens cases used for wet or dry shipping are:

1. B&L Boston Simplus case, which is supplied with the Boston SIMPLUS care solution, is cleared under K024289

2. Menicon Unique pH case, which is supplied with the Menicon Unique pH care solution is cleared under K130805

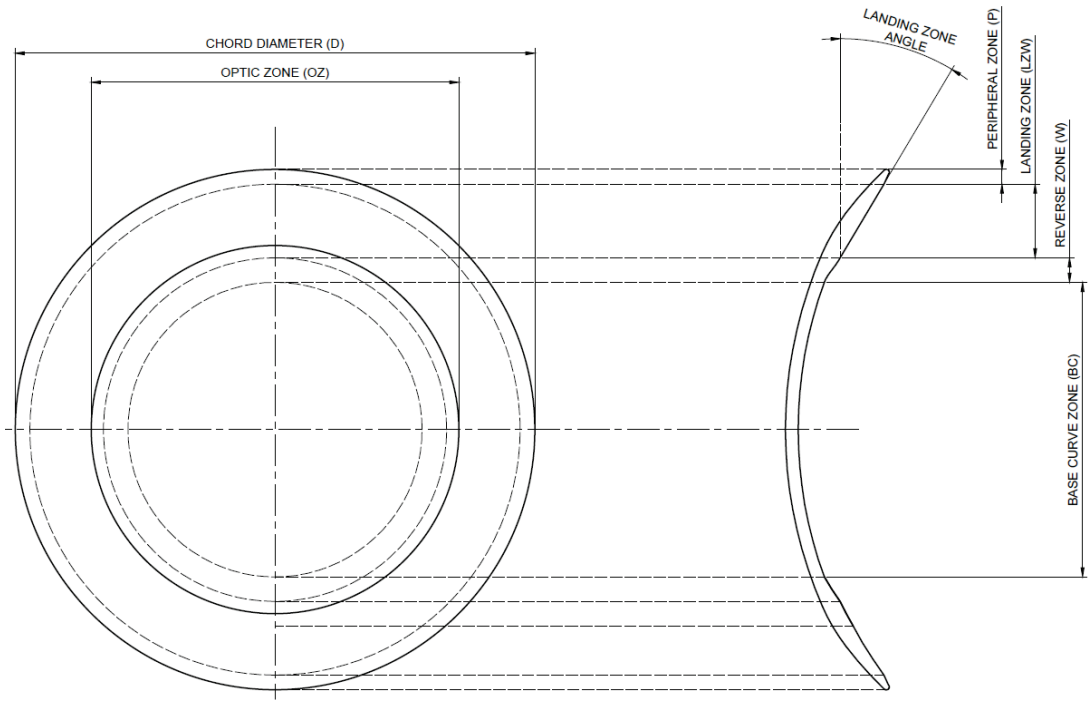
Table 1. Optimum Infinite (tisilfocon A) Orthokeratology Lenses II Parameters

Parameter	Range
Diameter (D)	9.5 to 12.0 mm
Central Base Curve Radius (BC)	6.50 to 10.50 mm
Optical Zone Semi Chord (OZ)	2.50 to 3.50 mm
Return Zone Width (w)	0.75 to 1.5 mm
Return Zone Depth (△)	to 1.0 mm
Return Zone Radius	to infinity
Landing Zone Angle (°)	-25° to -50°
Landing Zone Width (LZW)	0.5 to 2.75 mm
Peripheral Edge Curve Width (P)	0.04 mm to LZW
Dioptric Powers	-2.00 to +2.00 Diopters

Table 2. Optimum Infinite (tisilfocon A) Orthokeratology Lenses II Properties

Property	Optimum Infinite (tisilfocon A) Orthokeratology Lenses II
Refractive Index (dry)	1.434
Modulus (MPa)	1416
Hardness (Shore D)	81
Specific Gravity	1.20
Surface Character	Hydrophobic
Oxygen Permeability (Dk)	180×10^{-11} (cm^2/sec) (ml O_2/ml x mm Hg @ 35^oC)
Color Additives	Visibility Tints – D&C Green #6, Solvent Yellow #18, D&C Red #17

Figure 1. Optimum Infinite (tisilfocon A) Orthokeratology Lenses II Drawing



VI. ALTERNATIVE PRACTICES AND PROCEDURES

There are several other alternatives for the correction of refractive myopia; these 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. Each alternative has its own advantages and disadvantages. A patient should fully discuss these alternatives with his/her physician to select the method that best meets expectations and lifestyle.

VII. MARKETING HISTORY

The Optimum Infinite (tisilfocon A) Orthokeratology Lenses II have not been marketed in the United States or any foreign country.

VIII. POTENTIAL ADVERSE EFFECTS OF THE DEVICE ON HEALTH

Below is a list of the potential adverse effects (e.g., complications) associated with the use of the device. Potential adverse effects on health associated with contact lenses worn overnight include complications such as:

- corneal ulcers
- epithelial microcysts
- infiltrates

- 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.

For the specific adverse events that occurred in a clinical study, please refer to the SSED for P050031.

IX. SUMMARY OF NON-CLINICAL STUDIES

Non-clinical testing conducted on the Optimum Infinite (tisilfocon A) Orthokeratology Lenses II included analysis of biocompatibility, physical and optical properties, analysis of extractable residual components, bioburden testing, stability testing, preservative uptake and release, and manufacturing design validation. A summary of test results is provided below:

A. Laboratory Studies

1. Biocompatibility Testing (see Table 3 below) was performed on final finished lenses in accordance with relevant parts of International Standard Organization (ISO) 10993, Biological evaluation of medical devices standard series. All tests were conducted in accordance with provisions of 21 CFR 58, Good Laboratory Practice (GLP) for Nonclinical Laboratory Studies.

   The final finished Optimum Infinite (tisilfocon A) Orthokeratology Lenses II used for biocompatibility testing included the color additives D&C Green #6, Solvent Yellow #18, and D&C Red #17. Lenses were packaged using Boston SIMPLUS® as the primary packaging solution (for wet shipping). Lenses were removed from packaging solution prior to extraction.

Table 3. Summary of Biocompatibility Tests (Lens Extracts)

Test (ISO Standard)	Test Description	Results
Acute systemic toxicity (ISO 10993-11)	Acute systemic injection toxicity study in Hla® (ICR) CVF® mice, including polar and non-polar lens extracts	Passed
Acute ocular irritation (ISO 10993-23)	Acute ocular irritation in New Zealand White Rabbits,	Passed

	including polar and non-polar lens extracts	
Cytotoxicity (ISO 10993-5)	ISO MEM elution assay with L929 mouse fibroblasts cells	Passed

No additional biocompatibility testing was done for the different primary packaging solutions for wet shipping or the lens cases used for shipping, since these components are being used for device packaging without any modification and have been cleared under 510(k)s held by other manufacturers (as listed in the Device Description Section of this SSED document).

B. **Additional Studies**

1. Physicochemical tests
   Physicochemical tests were performed to demonstrate long term safety and stability of the properties of the material used to manufacture the Optimum Infinite (tisilfocon A) Orthokeratology Lenses II. See the following table for a summary of results.

Table 4. –Summary of Non-Clinical Testing

Test	Purpose	Measurement	Acceptance Criteria	Results
Physical and Optical Parameters				
Oxygen Permeability (x 10^{-11} (cm^2/sec) (ml O_2/ml x mm Hg @ 35°C)) (ANSI Z80.20)	To evaluate the oxygen transmissibility of the device	180	± 20%	Passed
Refractive Index (ANSI Z80.20)	To evaluate the refractive index of the device	1.433	1.434 ± 0.002	Passed
Light Transmittance (380-780nm, ct = 0.3mm) (ANSI Z80.20)	To evaluate the visible light transmissibility of the device	Blue: 92.0% Green: 91.5% Red: 95.3% Yellow: 94.5%	± 5%	Passed
UVA Transmittance (315-380nm, ct = 0.15mm) (ANSI Z80.20)	To evaluate the UVA light transmissibility of the device	Blue: 19.9% Green: 19.9% Red: 20.1% Yellow: 19.0%	<50%	Passed
UVB Transmittance (280-315nm, ct = 0.15mm) (ANSI Z80.20)	To evaluate the UVB light transmissibility of the device	Blue: 0.1% Green: 0.1% Red: 0.1% Yellow: 0.1%	<5%	Passed

Wetting Angle (Static Captive Bubble) (ANSI Z80.20)	To evaluate the wettability of the device	38°	38 ± 10°	Passed
Water Content (ANSI Z80.20)	To evaluate the water content of the device	0.21%	≤ 1%	Passed
Shore D Hardness (rest) (ASTM D2240)	To evaluate the mechanical properties of the device	81	81 ± 0.03	Passed
Flexural Modulus (MPa) (ANSI Z80.20)	To evaluate the mechanical properties of the device	1416	1500 ±200	Passed
Extraction Testing				
Soxhlet extraction in distilled water	To quantify and assess the device extractables	The extractables measured within the acceptance criteria for all color variants of the device	≤ 1.0%	Passed
Soxhlet extraction in n-hexane	To quantify and assess the device extractables	The extractables measured within the acceptance criteria for all color variants of the device	≤ 2.6%	Passed
UV and Color Migration				
FDA Guidance Premarket Notification (510(k)) Guidance Document for Daily Wear Contact Lenses	To determine the potential exposure to color additives or UV absorbers from contact lenses using a migration study	The color and UV migration of all Optimum Infinite variants tested was found to be below the Limit of Detection (LOD).	Performance test for characterization purposes only	Passed

2. Compatibility Testing

A study was conducted to evaluate the compatibility of Optimum Infinite (tisilfocon A) Orthokeratology Lenses II with representative contact lens care products on the market.

Table #5 Contact Lens Solution Compatibility Testing

Test	Purpose	Measurement	Acceptance Criteria	Results
Solution Compatibly Testing				
Solution compatibility testing (ISO 11981)	To evaluate the physical parameters of the lenses following	All parameters tested were within tolerance of the finished device specifications	The physical parameters of the lenses must remain within tolerance of	Passed

30 cycles with contact lens care solutions	following the 30 cycles	the finished device specifications	

3. Bioburden

Bioburden evaluations were conducted on lenses packaged in the dry state and lenses packaged in the wet state. Bioburden evaluations were conducted with acceptance criteria of < 100 Colony Forming Units (CFUs) per lens. Bioburden testing was validated with suitability testing.

Table #6 Summary of Bioburden Testing

Test	Purpose	Measurement	Acceptance Criteria	Results
Bioburden Testing				
Bioburden testing (ISO 11737-1)	To assess the level of microbial contamination on the lenses	< 1 Colony Forming Units (CFUs) for all lenses tested	< 100 CFUs per lens	Passed

4. Lens Stability

One month stability studies have been conducted on the non-sterile Optimum Infinite (tisilfocon A) Orthokeratology Lenses II packaged in Boston Simplus solution, Unique pH solution, and OTE JSZ Multi-Action solution.

Table #7 Summary of Shelf-Life Stability Testing

Test	Purpose	Measurement	Acceptance Criteria	Results
Stability Testing				
Stability testing	To evaluate the shelf-life of the finished lens specifications after 30 days storage in solution (wet).	All parameters tested were stable or within tolerance of the finished device specifications following the 30-day wet storage period.	The parameters tested must remain within tolerance of the finished device specifications	Passed

5. Lens design verification

A manufacturing design validation study of the Optimum Infinite (tisilfocon A) Orthokeratology Lenses II was conducted. The lens parameters were evaluated to the finished lens specifications within tolerances specified in ANSI Z80.20.

Table #8 Summary of Lens Manufacturing Validation Testing

Test	Purpose	Measurement	Acceptance Criteria	Results
Validation of the Lens Manufacturing Process				
Manufacturing design validation (ANSI Z80.20)	To demonstrate that the lens parameters of finished device are consistent with the finished device specifications	All parameters measured were within tolerance of the finished device specifications	Measured parameters must be within ANSI Z80.20 tolerance of finished device specifications	Passed

X. SUMMARY OF PRIMARY CLINICAL STUDY(IES)

The Optimum Infinite (tisilfocon A) Orthokeratology Lenses II has not been the subject of a published clinical study. Contamac, Ltd. is relying on the "six-year rule" as described in Section 216 of the Food and Drug Administration Modernization Act of 1997 (FDAMA) and the FDA guidance, "Guidance on Section 216 of the Food and Drug Administration Modernization Act of 1997," to use the clinical data supporting a previous PMA application of the Paragon Z CRT (tisilfocon A) Rigid Gas Permeable Contact Lenses for Contact Lens Corneal Refractive Therapy (P050031), approved on November 16th, 2006, to support the reasonable assurance of safety and effectiveness of the subject Optimum Infinite (tsilifocon A) Orthokeratology Lenses II because the two devices have the same material, specifications, and design. The safety and effectiveness of the Paragon Z CRT (tisilfocon A) Rigid Gas Permeable Contact Lenses for Contact Lens Corneal Refractive Therapy (P050031) was primarily supported by one pivotal study conducted in the United States (US) and a post-approval study (PAS) that was required as a condition of approval of the PMA. A brief overview and summary of the primary clinical study is presented below. Additional details regarding the US pivotal study of the Paragon Z CRT (tisilfocon A) Rigid Gas Permeable Contact Lenses for Contact Lens Corneal Refractive Therapy can be found in the P050031 SSED (https://www.accessdata.fda.gov/cdrh_docs/pdf5/P050031B.pdf).

Pivotal trial

A. Study Design

The pivotal study of the Paragon Z CRT corneal refractive therapy lenses was a prospective, multi-center, nonrandomized clinical study to evaluate the safety and effectiveness of the Paragon Z CRT corneal refractive therapy lenses worn overnight to treat myopia. The pivotal clinical study for P050031 included 204 eyes of 102

enrolled subjects, of which 196 eyes of 98 subjects were treated. There were 9 investigational sites. The study included both adults and adolescents ≥ 12 years.

1. Follow-up Schedule
   All patients 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 key timepoints are shown below in the tables summarizing safety and effectiveness.

2. Clinical Endpoints

   With regards to safety, the endpoints used to evaluate the safety of the treatment were:
   - 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.

   With regards to effectiveness, the endpoints used to evaluate the effectiveness of the treatment were:

   - 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.

B. Accountability of PMA Cohort

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%.

C. Study Population Demographics and Baseline Parameters

The demographics of the study population are typical for an orthokeratology study performed in the US.

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. Safety and Effectiveness Results

1. Safety Results

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

Table 9 below summarizes the findings related to these events.

Table 9

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

Table 10

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 in one subject who discontinued lens wear and was treated with medication resolved in 7 days. A second subject had two occurrences 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 Best Spectacle Corrected Visual Acuity (BSCVA), reductions to ≤ 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 ≤ 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 11.

Table 11

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††	16.3	9	5.4	4	2.5	2	1.2	4	2.5	5	3.5	7	3.3
BSCVA worse than 20/40 ***	4	2.0	3	1.8	1	0.6	0	0	1	0.6	1	0.7	2	1.0
Increase of > 1 D Refractive Cyl	2	1.0	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	8.2	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)

There 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.

2. Effectiveness Results

The analysis of effectiveness was based on the 137 evaluable eyes at the 6-month time point. Key effectiveness outcomes are presented below.

Average Reduction in Myopia

The average amount of myopia that can be expected to be corrected is shown in Table 12. 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 12

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 belter visual acuity at 6 months (Table 13).

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 treated eyes is also shown in Table 13.

Table 13

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%

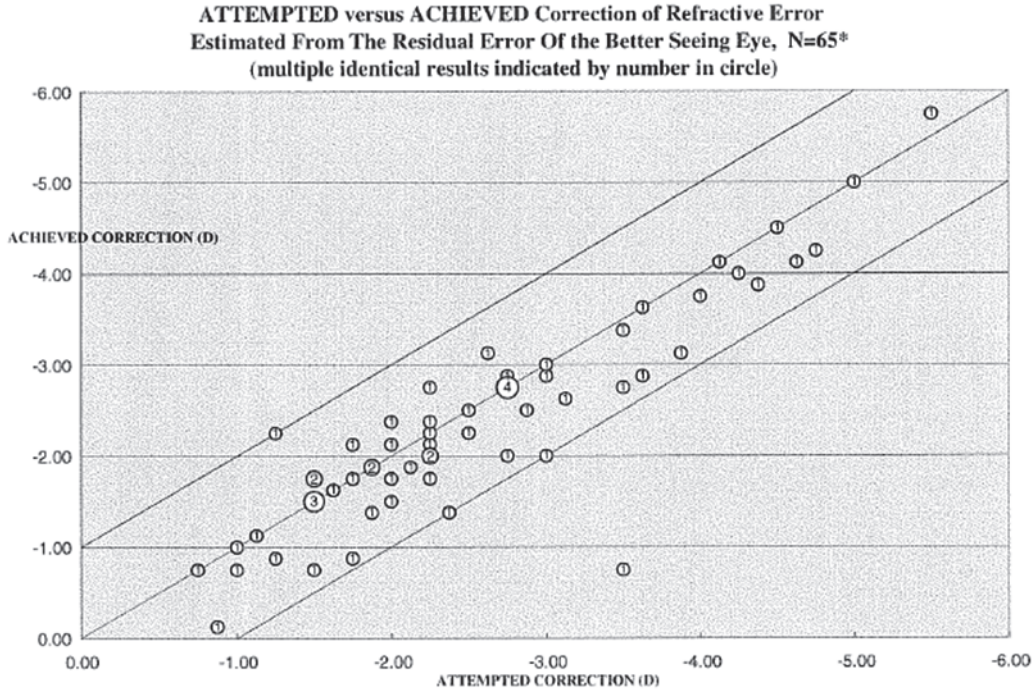
* N=144 for reduction (all efficacy qualified eyes)
** N=137 for Final VA (only eyes targeted for emmetropia)

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) 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 or initial myopia with treatment success.

There is reference in a published study[1] 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 or 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.

Figure 2



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

Wearing Time

[1] 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

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 14 represent 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 14

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.

3. Subgroup Analyses

No analyses were performed for sex, age, race, ethnicity, or any other specific subgroups.

4. Pediatric Extrapolation

In this premarket application, existing clinical data was not leveraged to support approval of a pediatric patient population.

XI. FINANCIAL DISCLOSURE

N/A

XII. PANEL MEETING RECOMMENDATION AND FDA'S POST-PANEL ACTION

In accordance with the provisions of section 515(c)(3) 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. CONCLUSIONS DRAWN FROM PRECLINICAL AND CLINICAL STUDIES

A. Effectiveness Conclusions

The effectiveness of the Optimum Infinite (tisilfocon A) Orthokeratology Lenses II was assessed with non-clinical data providing a direct comparison of the Optimum Infinite (tisilfocon A) Orthokeratology Lenses II to the FDA approved, commercially available Paragon Z CRT (tisilfocon A) Rigid Gas Permeable Contact Lenses for Contact Lens Corneal Refractive Therapy (P050031). The clinical data supporting a previous PMA application of the Paragon Z CRT (tisilfocon A) Rigid Gas Permeable Contact Lenses for Contact Lens Corneal Refractive Therapy (P050031) approved on November 16th, 2006 demonstrated that 94.8% of eyes achieved visual acuity of 20/40 or better at 6 months. The results of the non-clinical testing demonstrated that the Optimum Infinite (tisilfocon A) Orthokeratology Lenses II has the same material, specifications, and design as the Paragon Z CRT (tisilfocon A) Rigid Gas Permeable Contact Lenses for Contact Lens Corneal Refractive Therapy (P050031) This information provides a 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.

B. Safety Conclusions

The risks of the Optimum Infinite (tisilfocon A) Orthokeratology Lenses II are based on nonclinical laboratory studies as well as data collected to assess the safety and effectiveness of the commercialized Paragon Z CRT (tisilfocon A) Rigid Gas Permeable Contact Lenses for Contact Lens Corneal Refractive Therapy (P050031) since Contamac, LTD is relying on the "six-year rule" as described in Section 216 of the Food and Drug Administration Modernization Act of 1997 (FDAMA) and the FDA guidance, "Guidance on Section 216 of the Food and Drug Administration Modernization Act of 1997," to use the clinical data supporting a previous PMA application of the Paragon Z CRT (tisilfocon A) Rigid Gas Permeable Contact Lenses for Contact Lens Corneal Refractive Therapy (P050031) approved on November 16th, 2006, to support the reasonable assurance of safety and effectiveness of the subject Optimum Infinite (tisilfocon A) Orthokeratology Lenses II because the two devices have the same material specifications and design. The nonclinical laboratory studies demonstrate that the Optimum Infinite (tisilfocon A) Orthokeratology Lenses II has the same material and specifications as the commercialized Paragon Z CRT (tisilfocon A) Rigid Gas Permeable Contact Lenses for Contact Lens Corneal Refractive Therapy.

C. Benefit-Risk Determination

The probable benefits of the device are based on data collected in a clinical study conducted to support PMA approval of the Paragon Z CRT (tisilfocon A) Rigid Gas Permeable Contact Lenses for Contact Lens Corneal Refractive Therapy (P050031). As discussed in the P050031 SSED of the Paragon Z CRT (tisilfocon A) Rigid Gas Permeable Contact Lenses for Contact Lens Corneal Refractive Therapy, 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 belter visual acuity at 6 months. At the 6 month visit, 77.6% (111/144) 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. 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.

The probable risks of the device are also based on data collected in a clinical study conducted to support PMA approval of the Paragon Z CRT (tisilfocon A) Rigid Gas Permeable Contact Lenses for Contact Lens Corneal Refractive Therapy (P050031). As discussed in the P050031 SSED of the Paragon Z CRT (tisilfocon A) Rigid Gas Permeable Contact Lenses for Contact Lens Corneal Refractive Therapy, seventy percent of completed eyes (101/144) 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.

There were three adverse events reported. Two were rated as moderate and one was rated as mild. A peripheral corneal infiltrate reported in one subject who discontinued lens wear and was treated with medication resolved in 7 days. A second subject had two occurrences of corneal infiltrates which resolved in 6 days. This subject also discontinued lens wear and was administered medication.

No serious adverse events were reported.

1. Patient Perspective

   This submission either did not include specific information on patient perspectives or the information did not serve as part of the basis of the decision to approve or deny the PMA for this device.

In conclusion, given the available information above, the data support that for overnight wear for the temporary reduction of myopia up to 6.00 diopters with eyes having astigmatism up to 1.75 diopters, the probable benefits outweigh the probable risks.

D. Overall Conclusions

The data in this application support the reasonable assurance of safety and effectiveness of this device when used in accordance with the indications for use. The Optimum Infinite (tisilfocon A) Orthokeratology Lenses II is demonstrated to have the same design and material specifications as the commercialized Paragon Z CRT (tisilfocon A) Rigid Gas Permeable Contact Lenses for Contact Lens Corneal Refractive Therapy (P050031) for the same intended use. Therefore, Contamac, LTD is relying on the "six year rule" as described in Section 216 of the Food and Drug Administration Modernization Act of 1997 (FDAMA) and the FDA guidance, "Guidance on Section 216 of the Food and Drug Administration Modernization Act of 1997," to use the clinical data supporting a previous PMA application of the Paragon Z CRT (tisilfocon A) Rigid Gas Permeable Contact Lenses for Contact Lens Corneal Refractive Therapy (P050031) approved on November 16, 2006, to support the reasonable assurance of safety and effectiveness of the subject Optimum Infinite (tisilfocon A) Orthokeratology Lenses II. Results from non-clinical testing indicates that the Optimum Infinite (tisilfocon A) Orthokeratology Lenses II is functionally the same as the commercially available Paragon Z CRT (tisilfocon A) Rigid Gas Permeable Contact Lenses for Contact Lens Corneal Refractive Therapy.

XIV. CDRH DECISION

CDRH issued an approval order on February 10, 2026.

The applicant's manufacturing facility was inspected and found to be in compliance with the device Quality System (QS) regulation (21 CFR 820), which was in effect at the time of the inspection. As of February 2, 2026, the revised part 820, referred to as the Quality Management System Regulation (QMSR), is effective.

XV. APPROVAL SPECIFICATIONS

Directions for use: See device labeling.

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

Post-approval Requirements and Restrictions: See approval order.

XVI. REFERENCES

International Standard Organization 10993-5, Biological Evaluation of Medical Devices – Part 5: Tests for in vitro cytotoxicity

International Standard Organization 10993-23, Biological Evaluation of Medical Devices – Part 23: Tests for irritation

International Standard Organization 10993-11, Biological Evaluation of Medical Devices – Part 11: Tests for systemic toxicity

International Standard Organization 11737-1, Sterilization of health care products – Microbial methods – Part 1: Determination of a population of microorganisms on products

ANSI Z80.20 American National Standard for Ophthalmics – Contact Lenses – Standard Terminology, Tolerances, Measurements and Physicochemical Properties

International Standard Organization 11981, Ophthalmic optics – Contact lenses and contact lens care products – Determination of physical compatibility of contact lens care products with contact lenses

Guidance on Section 216 of the Food and Drug Administration Modernization Act of 1997 - Guidance for Industry and for FDA Reviewers

Premarket Notification (510(k)) Guidance Document for Daily Wear Contact Lenses