SUMMARY OF SAFETY AND EFFECTIVENESS DATA (SSED)

I. GENERAL INFORMATION

Device Generic Name:	Lens, contact, orthokeratology, overnight
Device Trade Name:	Dilight™ (roflufocon E) Overnight Orthokeratology Contact Lens
Device Procode:	NUU
Applicant's Name and Address:	Tianjin MasterVision Technology Co., Ltd. 1st Floor No.15 Building. No. 89 Heyuan Road, Jing-jin Technology Valley, Wuqing District, Tianjin. P.R. China
Date(s) of Panel Recommendation:	None
Premarket Approval Application (PMA) Number:	P220015
Date of FDA Notice of Approval:	08/05/2026

II. INDICATIONS FOR USE

The Dilight™ (roflufocon E) Overnight Orthokeratology Contact Lens is indicated for use in the reduction of myopic refractive error in non-diseased eyes. The lens is indicated for overnight wear for the temporary reduction of myopia up to 4.00 diopters (manifest spherical equivalent) in eyes with astigmatism up to 1.50 diopters. The lenses may only be disinfected using a chemical disinfection system.

Note: To maintain the Orthokeratology effect overnight lens wear must be continued on a prescribed schedule. Failure to do so can affect daily activities (e.g., night driving), cause visual fluctuations, and changes in intended correction.

III. CONTRAINDICATIONS

DO NOT USE YOUR Dilight™ (roflufocon E) Overnight Orthokeratology Contact Lens when any of the following conditions exist:

- Acute and sub-acute 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 which 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 the contact lens.
- Any active corneal infection (bacterial, fungal or viral).
- If eyes are red or irritated.

IV. WARNINGS AND PRECAUTIONS

The warnings and precautions can be found in the Dilight™ (roflufocon E) Overnight Orthokeratology Contact Lens labeling.

V. DEVICE DESCRIPTION

The Dilight™ (roflufocon E) Overnight Orthokeratology Contact Lens is a lathe cut contact lens manufactured from the rigid gas permeable material roflufocon E, which is a fluorosilicone acrylate contact lens material registered with the United States Adopted Names (USAN) Council.

Th Dilight™ (roflufocon E) Overnight Orthokeratology Contact Lens incorporates a visibility tint to make the lens more visible for handling. The tinted lenses are available in blue and gray, and contain one or more of the following color additives: D&C Green No.6, C.I. Solvent yellow No. 18, and FD&C Red No. 17.

The parameters and physical properties of the Dilight™ (roflufocon E) Overnight Orthokeratology Contact Lens are as follows:

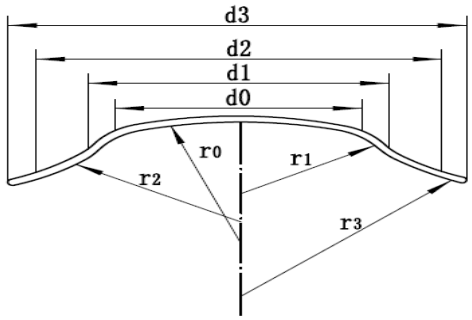
Table 1 - Dilight™ (roflufocon E) Overnight Orthokeratology Contact Lens

Parameter or Property	Specification	Tolerance Limit
Radius of Base Arc Curvature	7.50-9.93 mm, Step Size 0.01mm	±0.05 mm
Total Diameter	9.60-11.60 mm, Step Size 0.10 mm	±0.10 mm
Central Thickness	0.15-0.30 mm, Step Size 0.01 mm	±0.02 mm
Back Focal Power F'v	$\|F'v\| \leq 5.00D$ $5.00D < \|F'v\| \leq 10.00D$	±0.12D ±0.18D
Prismatic Power (Residual)	$\|F'v\| \leq 6.00D$ $\|F'v\| > 6.00D$	±0.25cm/m ±0.50cm/m

Oxygen Permeability	94×10^{-11} (cm^2/s) [$mLO_2/(mL\cdot hPa)$] @35℃	± 20%
Refractive Index	1.432	± 0.001
Specific Gravity	1.15	-
Light Transmittance	94 %	± 5%
Contact Angle	46°	± 15%
Water Absorption	Less than 0.5% by weight	-

The Dilight™ (roflufocon E) Overnight Orthokeratology Contact Lens is designed with anti-geometric shape. The lens consists of four arcs (or curves): base arc, reverse arc, fitting arc and side arc. The basal arc region, located in the center and relatively flat in shape, is the treatment area and exerts slight pressure on the cornea. The second is the inverted arc region, which is steeper and provides space for corneal epithelium and tear fluid. The fitting arc zone is then used to provide pressure in the middle and periphery of the cornea and improve center positioning. The lateral arc is the site of tear exchange.

Figure 1 Schematic Diagram of Shaft Section of Orthokeratology



r_0 ——BC Base Arc Radius;
r_1 —— Reverse Arc Curvature Radius;
r_2 ——Adaptive Arc Curvature Radius;
r_3 ——Edge Arc Curvature Radius;
d_0 ——Base Arc Diameter;
d_1——Reverse Arc Diameter;
d_2——Adaptive Area Diameter;
d_3——Total Diameter;

VI. ALTERNATIVE PRACTICES AND PROCEDURES

There are several other alternatives for the correction of myopia.

The alternative practices and procedures for the temporary correction of myopia 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 for permanent treatment.
Each alternative has its own advantages and disadvantages. A patient should fully discuss these alternatives with his/her eye care provider to select the method that best meets expectations and lifestyle.

VII. MARKETING HISTORY

The Dilight™ (roflufocon E) Overnight Orthokeratology Contact Lens is currently approved in China. The lens has not been withdrawn from marketing in any market for any reason related to its safety or effectiveness.

VIII. POTENTIAL ADVERSE EFFECTS OF THE DEVICE ON HEALTH

Potential adverse effects on health associated with contact lenses worn overnight include complications such as corneal ulcers, Acanthamoeba Keratitis (AK), 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.
For the specific adverse events that occurred in the clinical studies, please see Section X below.

IX. SUMMARY OF NON-CLINICAL STUDIES

Non-clinical testing performed on the Dilight™ (roflufocon E) Overnight Orthokeratology Contact Lens include: biocompatibility, physical and optical properties, extractable residual components, and bioburden testing. The application includes by reference the following non-clinical tests from K033594 (Optimum GP (Oxygen Permeable) Daily Wear Contact Lenses, Contamac, Inc.), which is made of the same lens material: lens solution compatibility study, preservative uptake and release study, and mechanical properties testing. The shelf-life stability testing is not needed since the lenses are shipped dry. A summary of test results conducted by the Applicant on the subject device is provided below:

A. Laboratory Studies

1) Biocompatibility Testing
Biocompatibility testing (see Table 2 below) was performed on the Dilight™ (roflufocon E) Overnight Orthokeratology Contact Lens in accordance with relevant parts of International Standard Organization (ISO) 10993, Biological evaluation of

medical devices standard series and ISO 9394:2012 Ophthalmic optics- Contact lenses and contact lens care products- Determination of biocompatibility by ocular study with rabbit eyes. All tests were conducted in accordance with provisions of 21 CFR 58, Good Laboratory Practice (GLP) for Nonclinical Laboratory Studies.

Table 2: Summary of Biocompatibility Tests

Test (ISO Standard)	Test Description	Results
Cytotoxicity (ISO 10993-5:2009)	ISO MEM elution assay with L929 mouse fibroblasts cells	Non-cytotoxic
Sensitization (ISO 10993-10:2021)	ISO Guinea Pig Maximization study	Non-sensitizing
Irritation (ISO 10993-23:2021)	Ocular irritation study	Non-irritant
Acute Systemic Toxicity (ISO 10993-11:2017)	ISO acute systemic injection toxicity test	Non-toxic
Ocular Study (ISO 9394:2012)	22-day contact lens wear study in rabbits with slit-lamp microscopy, histology, and assessment of corneal metabolism	Dilight™ Overnight Orthokeratology Contact Lens did not induce adverse effects in rabbit's eyes.

2) Physicochemical Tests

Physicochemical tests were performed with results consistent with ANSI Z80.20 - for Ophthalmics – Contact Lenses – Standard Terminology, Tolerances, Measurements and Physicochemical Properties, and ISO 18369-3 – Ophthalmic optics – Contact lenses – Part 3: Measurement methods, and ISO 18369-4 – Ophthalmic optics – Contact lenses – Part 4: Physicochemical properties of contact lens materials, to demonstrate long term safety and stability of the properties of the material used to manufacture the Dilight™ (roflufocon E) Overnight Orthokeratology Contact Lens. See the Table 3 for a summary of results.

Table 3 – Summary of Non-Clinical Testing

Test	Purpose	Measurement	Acceptance Criteria	Results
Physical and Optical Parameters				
Oxygen Permeability	To evaluate the oxygen transmission of the lens material	97×10^{-11} (cm^2/s) [$mLO_2/(mL\cdot hPa)$] @35 ℃	$94\times10^{-11} \pm 20\%$ (cm^2/s) [$mLO_2/(mL\cdot hPa)$] @35 ℃	Passed
Refractive Index	To evaluate the refractive index of the device	1.431	1.432 ± 0.002	Passed
Light Transmittance	To evaluate the visible light transmissibility of the device	94 %	94%±5	Passed
Contact Angle	To evaluate the wettability of the device	41°	46 ± 15%	Passed

Extraction Testing				
Soxhlet extraction in distilled water	To quantify and assess the device extractables	Blue: 0.25% Grey:0.23%	Not more than 1.0%	Passed
Soxhlet extraction in n-hexane	To quantify and assess the device extractables	Blue: 1.71% Grey:1.76%	Not more than 3.0%	Passed
Soxhlet extraction in dichloromethane	To quantify and assess the device extractables	Blue: 2.07% Grey:1.93%	Not more than 3.0%	Passed

3) Bioburden

The Dilight™ (roflufocon E) Overnight Orthokeratology Contact Lens is supplied dry (not in solution) in non-sterile packaging. Bioburden evaluations were conducted with acceptance criteria of < 100 Colony Forming Units (CFUs) per lens. Bioburden testing was validated with suitability testing consistent with ISO 11737-1:2018 - Sterilization of health care products – Microbiological methods – Part 1: Determination of a population of microorganisms on products.

Table 4 Summary of Bioburden Testing

Test	Purpose	Measurement	Acceptance Criteria	Results
Bioburden Testing				
Bioburden testing	To assess the level of microbial contamination on the lenses	17.9 Colony Forming Units (CFUs) per lens	< 100 Colony Forming Units (CFUs) per lens	Passed

4) Lens design verification

A manufacturing design validation study of the Dilight™ (roflufocon E) Overnight Orthokeratology Contact Lens was conducted. The lens parameters were evaluated against the finished lens specifications consistent with ANSI Z80.20 and found to be within tolerances.

Table 5 Summary of Lens Manufacturing Validation Testing

Test	Purpose	Measurement	Acceptance Criteria	Results
Validation of the Lens Manufacturing Process				
Manufacturing design validation	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 tolerance of finished device specifications as specified in ANSI Z80.20	Passed

X. SUMMARY OF PRIMARY CLINICAL STUDY

The applicant performed a clinical study to establish a reasonable assurance of safety and effectiveness of the Dilight™ (roflufocon E) Overnight Orthokeratology Contact Lens to temporarily reduce myopic refractive error compared with a control lens. Data from this clinical study along with a Supplemental Study (see study summary in Section XII) were the basis for the PMA approval decision. A summary of the pivotal clinical study is presented below.

A. Study Design

Patients were treated between Dec. 28, 2016, and Jan. 28, 2019. The database for this PMA reflected data collected through Nov. 1, 2019 and enrolled 280 patients. There were three investigational sites located in China.

The pivotal study was a multi-center, randomized, open label, active, parallel controlled clinical study. 215 subjects completed all the follow-up visits as specified in the study protocol—including 109 subjects from the test group and 106 subjects from the control group. The subjects were randomized 1:1 to the experimental and the control groups.

Subjects in the control group were treated with rigid gas permeable contact lenses for orthokeratology (Euclid (tisilfocon A) overnight orthokeratology contact lens, FDA approved (P040029)), and those in the test group were treated with the Dilight™ (roflufocon E) Overnight Orthokeratology Contact Lens produced by Tianjin Mastervision Technology Co., Ltd.

1. Clinical Inclusion and Exclusion Criteria

   Enrollment in the study was limited to patients who met the following inclusion criteria:

   1) Binocular myopic patients aged 8 to 40 (including 8 and 40) without gender limitations;
   2) Myopia of 4.00D or lower;

3) For the cylindrical degree, the astigmatism with rule is lower than 1.75D, and astigmatism against rule is lower than 1.00D;
4) BCDVA is not lower than 20/20;
5) Corneal curvature is within 40.00D~46.00D;
6) Stable refractive error values before treatment;
7) At least 1-year follow-up visit can be carried out and the patient can wear the lenses for 8~10 hours every day;
8) The patient has not worn rigid contact lenses (including orthokeratology lens) in the past 2 months.
9) The patient has not participated in any clinical trials of other drugs or medical devices within 30 days before the screening;
10) The patient can understand the purpose of the trial and voluntarily participate; the patient himself/herself or his/her legal guardian shall sign the informed consent.

Patients were not permitted to enroll in the study if they met any of the following exclusion criteria:

1) The patient has systemic diseases to have caused low immunity or has an influence on orthokeratology (such as acute and chronic sinusitis, diabetes, Down syndrome, rheumatoid arthritis, and mental disorders);
2) The patient has an abnormal cornea, has ever received corneal surgery or has a history of corneal trauma; active keratitis (such as corneal infection), decreased corneal sensation, a history of ocular trauma or intra-ocular surgery, fundus lesions, or other organic diseases of eyes;
3) The patient has other eye diseases, such as inflammation including dacryocystitis, xerophthalmia, conjunctivitis, blepharitis, etc., and glaucoma:
4) The patient is pregnant or in a lactating period, or plans to get pregnant;
5) The patient is using or needs to use drugs that may cause dry eyes or affect eyesight, corneal curvature, etc.;
6) The patient is allergic to contact lenses or their care solutions;
7) The pupil diameter is larger than 6.2 mm;
8) Other conditions in which the investigators judge that the patient is not suitable for the clinical trial.

2. Follow-up Schedule

Follow-up visits were carried out for subjects after 1 day, 1 week, 2 weeks, 30 days, 3 months, 6 months, 9 months, and 12 months of wearing the contact lenses.

3. Clinical Endpoints: Pivotal Study

Safety Endpoints:

Safety analyses were conducted on the Safety Data Set (SDS), which included data from subjects who underwent at least one treatment and had safety indicator records. The missing value of safety does not need to be carried forward.

With regards to safety, adverse events were described by the frequency, the number, and the incidence rate of adverse events. The specific details and severity of all adverse events, and their relationship with the test device, were also reported.

The following are the prespecified Safety Endpoints analyses to establish the safety of the device:

- The incidence rate of abnormal symptoms (any aberrant reports by subjects regarding discomfort, pain, etc.,) abnormal signs (any unusual objective findings reported after Slit lamp Exam (SLE) & Fluorescein (FL) staining) , complications and adverse events of the subjects after 1 day, 1 week, 2 weeks, 30 days, 3 months, 6 months, 9 months and 12 months of wearing;

- Corneal topography parameters of subjects after 1-day, 1-week, 2-weeks, 30-days, 3-month, 6-month, 9-month and 12-months of wearing

- Corneal thickness, corneal endothelial cell density and their changes in subjects after 30 days and 12 months of wearing

- Proportion of subjects whose best corrected visual acuity (BCVA) decreased by 1 line, 2 lines, or more than 2 lines compared with baseline after 1 day, 1 week, 2 weeks, 30 days, 3 months, 6 months, 9 months, and 12 months of wearing (presented in Snellen or Logarithm of the Minimum Angle of Resolution Visual Acuity (LogMAR VA))

- Proportion of subjects whose cylinder power increases by less than 1.00D, 1.00D to 2.00D, or 2.00D or more compared with baseline after 1 day, 1 week, 2 weeks, 30 days, 3 months, 6 months, 9 months and 12 months after contact lens wear

- Intra-ocular pressure (IOP) after 30-days and 12-months of contact lens wear

- Subjects' adaptability to orthokeratology lenses after 1-day, 1-week, 2-weeks, 30-days, 3-months, 6-months, 9-months and 12-months of contact lens wear

- The damage rate, scratches, protein precipitation, etc. of lenses after 1-day, 1-week, 2-weeks, 30-days, 3-months, 6-months, 9-months and 12-months of contact lens wear

The following additional analyses were also evaluated to establish the safety of the device:

- Signs/Symptoms, Complications, Adverse Events, Slit Lamp Findings; Keratometry readings /Corneal Topography and noted changes of the subjects after 1 day, 1 week, 2 weeks, 30 days, 3 months, 6 months, 9 months and 12 months of wearing the contact lens and the associated grading scales for these findings
  - The endpoint evaluated the proportion of eyes with Slit Lamp Findings greater than Level 2 at any follow-up visit. (all positive and negative (grade 0) findings were also recorded

- Keratometry / corneal topography data was analyzed for trends such as:
  - the tendency toward corneal sphericity or toricity,
  - the correlation of K changes to fitting relationship (initial K reading to lens base curve selected)
  - the amount of refractive change from initial to final visit

- Study discontinuations and clinical reasons

- Lens/ Device Replacements

Effectiveness Endpoints:

The following were the key effectiveness endpoints for approvability:

- Uncorrected (distance) visual acuity (UCVA) of subjects after 30 days of wearing the orthokeratology contact lens:
  Percentage of subjects whose UCVA of both eyes reaches 20/25.

- Residual refractive error of subjects after 30 days of wearing the orthokeratology contact lens: Percentage of subjects whose residual refractive error of both eyes is less than ±0.5D.

With regards to effectiveness, study populations were analyzed for non-inferiority according to the following groups:

Full Analysis Set (FAS): This set was determined based on the intention to treat and consists of all subjects who participated in the treatment and have at least one effectiveness evaluation.

Per Protocol Set (PPS): This is a subset of the FAS data set which is more compliant with the testing scheme. The requirements refer to the set of subjects that meet the enrollment criteria, have no serious protocol violations,

and have completed all scheduled visits (no missing primary effectiveness indicators) for analysis (PP analysis).

Additional effectiveness endpoints

- Percent of eyes at 12 months that are within ±0.50 D, and percent within ±1.00D of target MRSE and

- Percent of eyes at 12 months that achieve UCDVA of 20/20 or better, and percent that achieve 20/40 or better,

Note: for results on these particular outcomes, see the Safety and Effectiveness Endpoint section.

The following are the secondary endpoints:

- Uncorrected visual acuity (UCVA) after 1 day, 1 week, 2 week, 30 days, 3 months, 6 months, 9 months and 12 months of wearing

- The refractive error after 1 day, 1 week, 2 weeks, 30 days, 3 months, 6 months, 9 months and 12 months of wearing;

- The corneal K value after 1 day, 1 week, 2 weeks, 30 days, 3 months, 6 months, 9 months and 12 months of wearing

The following additional data and analyses were also provided to help characterize the effectiveness of the device:

- Mean reduction in (Manifest Refractive Spherical Equivalent) MRSE from baseline to 12 month (all eyes)- overall and stratified by baseline MRSE

- Percent of eyes at 12 months that are within ±0.50, ±1.00, and ±2.00 ±3.00 of MRSE target

- Stability defined by the following quantifiable measures:

– Mean change in spherical refraction between two consecutive visits
– The percent of eyes changing <=1.00 D MRSE between two consecutive time points at least two months apart

B. Accountability of PMA Cohort

At the time of database lock, of 280 patients enrolled in the PMA study, 215 patients (76.8%) were available for analysis at the completion of the study, the 12-month treatment visit.

Three investigational sites enrolled 280 subjects (140 subjects randomized into the test group and 140 subjects into the control group respectively). Among the subjects, 215 subjects completed all the follow-up visits as specified in the study protocol—including 109 subjects from the experimental group and 106 subjects from the control group. 65 subjects dropped out and 10 subjects were terminated from the study, 252 subjects (124 from the test group, 128 from the control group) were classified into the FAS data set, 231 subjects (115 from the experimental group, 116 from the control group) were classified into the PPS data set, and 259 subjects (128 from the test group, 131 from the control group) were classified into the SDS data set.

Table 6 – Accountability at each scheduled visit

	Initial		Month 1		Month 3		Month 6		Month 9		Month 12	
	C	T	C	T	C	T	C	T	C	T	C	T
Available for Analysis (in Window) (n/N[1])%	262 (46.8%)	258 (46.1%)	240 (42.9%)	242 (43.2%)	232 (41.4%)	232 (41.4%)	226 (40.4%)	230 (41.1%)	216 (38.6%)	226 (40.4%)	212 (37.9%)	218 (38.9%)
Discontinued	16	22	18	16	6	8	4	2	4	0	2	4
Loss to Follow-up	2	0	4	0	2	2	2	0	6	4	2	4
% (n/N[2]) Accountability	262 (47.0%)	258 (46.2%)	240 (43.3%)	242 (43.7%)	232 (42.2%)	232 (42.2%)	226 (41.2%)	230 (42.0%)	216 (40.2%)	226 (42.0%)	212 (39.9%)	218 (41.0%)

n = total number of eyes in the specified column category at that visit
[1] N = total number of eyes enrolled (560)
[2] N = total number of eyes enrolled (560) – total number of eyes lost to follow-up

Note :
The reasons for withdrawing from the study included difficulty with handling and wearing the contact lenses (10), disinterest in wearing the contact lens (6), poor vision in low light or dimly lit environments (4), discomfort while wearing the lenses (4), and adverse reactions. events (4). A large portion of patients withdrew from the study for reasons unrelated to contact lens complications (58) or did not provide specific reasons for withdrawal **(**44**)**.

C. Study Population Demographics and Baseline Parameters

The demographics of the study population are atypical for a randomized, prospective, multi-center controlled clinical studies performed in the US.

Table 7 – Demographic Information

	Index	Test group	Control group	Total
Age (years)	N(Missing)	124(0)	128(0)	252(0)
	Mean(Sd)	18.24(8.85)	17.21(8.01)	17.71(8.43)
	Median	14.92	14.82	14.89
	Ql,Q3	11.64,24.69	10.99,23.17	11.44,24.06
	Min, Max	8.60,39.62	8.00,39.89	8.00,39.89
Gender	Male n (%)	32(25.81%)	58(45.31%)	90(35.71%)
	Woman n (%)	92(74.19%)	70(54.69%)	162(64.29%)
	Total (missing)	124(0)	128(0)	252(0)
Ethnic group	Han Chinese n (%)	112(90.32%)	120(93.75%)	232(92.06%)
	Other n (%)	12(9.68%)	8(6.25%)	20(7.94%)
	Total (missing)	124(0)	128(0)	252(0)

NOTE : N= total # in group at baseline ; n = number within Ethnic or Gender subgroup; % =n/ N

The clinical trial was designed to enroll three relatively evenly distributed age groups, 8-12, 13-18 and >18 year old patients, to allow for comparison of results across age groups. As a result, the average age of the patients enrolled in the study is 17.7 years old.

TABLE 8 The distribution of Baseline Myopic Refractive Errors

	Pretreatment Myopia (Spherical Diopters)													
	≤1.0 D		1.25 to 2.00 D		2.25 to 3.00 D		3.25 to 4.00 D		4.25 to 5.00 D		Not Report		Totals	
Corneal Astigmatism	n/%		n/%		n/%		n/%		n/%		n/%		n/%	
	Test	Control	Test	Control	Test	Control	Test	Control	Test	Control	Test	Control	Test	Control
0.00	0 (0.0%)	0 (0.0%)	1 (0.8%)	0 (0.0%)	2 (1.1%)	0 (0.0%)	1 (0.5%)	1 (0.5%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0(0.00%)	4(0.80%)	1 (0.20%)
＜0.12	0 (0.0%)	0 (0.0%)	1 (0.8%)	1 (1.1%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	1 (0.2%)
0.12 to 0.50	0 (0.0%)	1 (7.2%)	5 (4.9%)	8 (7.9%)	9 (5.0%)	8 (4.4%)	4 (2.4%)	8 (4.6%)	0 (0.0%)	1 (8.3%)	7 (32.0%)	3 (13.6%)	25 (5.0%)	29 (5.8%)
0.5 to 0.62	0 (0.0%)	0 (0.0%)	2 (1.6%)	0 (0.0%)	3 (1.7%)	4 (2.2%)	4 (2.3%)	2 (1.1%)	1 (8.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	10 (2.0%)	6 (1.2%)
0.62 to 1.00	2 (15.5%)	1 (8.3%)	6 (6.4%)	17 (16.0%)	15 (8.3%)	18 (9.9%)	14 (8.2%)	12 (6.9%)	0 (0.0%)	1 (16.7%)	4 (18.2%)	5 (22.7%)	41 (8.1%)	54 (10.7%)
1.00 to 1.12	0 (0.0%)	0 (0.0%)	3 (3.0%)	2 (1.9%)	1 (0.6%)	8 (4.4%)	5 (3.0%)	3 (1.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	9 (1.8%)	13 (2.6%)
1.12 to 1.50	2 (15.5%)	1 (8.3%)	7 (6.2%)	9 (7.5%)	9 (5.0%)	8 (4.4%)	12 (7.1%)	6 (3.4%)	0 (0.0%)	0 (0.0%)	1 (4.6%)	0 (0.0%)	31 (6.16%)	24 (4.77%)
1.50 to 1.62	0 (0.0%)	1 (7.2%)	1 (0.8%)	1 (1.1%)	1 (0.6%)	0 (0.0%)	5 (3.0%)	3 (1.8%)	0 (0.0%)	1 (8.3%)	0 (0.0%)	0 (0.0%)	7 (1.4%)	6 (1.2%)
1.62 to 2.00	0 (0.0%)	1 (8.3%)	0 (0.0%)	3 (2.7%)	3 (1.7%)	4 (2.2%)	5 (3.0%)	3 (1.8%)	0 (0.0%)	1 (16.7%)	0 (0.0%)	0 (0.0%)	8 (1.6%)	12 (2.4%)
＞2.00	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (1.1%)	0 (0.0%)	4 (2.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	6 (1.2%)	0 (0.0%)
Not Report	2 (14.3%)	2 (15.5%)	19 (17.3%)	22 (20.0%)	38 (21.0%)	48 (26.5%)	42 (24.7%)	37 (21.8%)	3 (33.3%)	1 (8.3%)	2 (9.1%)	0 (0.0%)	106 (21.0%)	110 (21.8%)
Totals	6 (45.2%)	7 (54.8%)	45 (41.8%)	63 (58.3%)	83 (45.9%)	98 (54.1%)	96 (56.4%)	75 (43.7%)	4 (41.7%)	5 (58.3%)	14 (63.6%)	8 (36.4%)	248 (49.2%)	256 (50.8%)

Percentage = number of eyes within both the corneal astigmatism range and myopia range, divided by the total number of eyes within the myopia range.

The clinical trial was conducted in China, and almost all the patients were Chinese Han nationality (92.32% in the test group, 93.75% in the control group).

Although the clinical study included only a Chinese racial distribution, the study outcomes were determined acceptable to support marketing approval in the US population based on the following considerations:

(1) Individually designed Dilight™ (roflufocon E) lens is based on the corneal shape of each specific patient (the lens geometry of the subject device is specifically designed and customized for each patient) and, therefore clinical performance of the device is not affected by the ethnicity of the wearer.

(2) Scientific literature reports no significant differences in orthokeratology effectiveness between Asian and Caucasian eyes (centration, eyelid tension, myopic reduction)[1,] .

[1] N. Tahhan; F. Sarfraz; N. Raad; C. Raad; T. Weber; R. Du Toit; E. Papas; Orthokeratology and the Eyelid Investigative Ophthalmology & Visual Science May 2003, Vol.44, 3714.

D. Safety and Effectiveness Results For Primary Clinical Study

1. Safety Results

The analysis of safety was based on the safety cohort of 259 subjects: 128 test subjects and 131 control subjects available for the 12 month evaluation. The key safety outcomes for this study are presented below in Table 15.

- **Signs/Symptoms, Complications, Adverse Events, Slit Lamp Findings**

  During the slit lamp examination at 1 day, 1 week, 2 weeks, 1 month, 3 months, 6 months, 9 months and 12 months after wearing the lenses, both the test and control groups reported complications including corneal epithelial shedding, corneal epithelial injury, corneal epithelial punctate staining, corneal neovascularization, and lens indentation. The test group also reported allergic conjunctivitis.

  Very few abnormalities in tear film examination (TBUT), corneal sensation testing and lens positioning were found in either the test group or the control group.

  Subjects underwent tear film evaluation after 1 day, 1 week, 2 weeks, 1 month, 3 months, 6 months, 9 months, and 12 months of wearing the orthokeratology contact lens. Abnormalities in fluorescein staining were found in both the test group and the control group. At 12 months, there were no abnormalities in the test group and 11 cases in the control group. The types of complications seen between the test and control subjects were similar and typical of those associated with orthokeratology wearers. There were no significant (i.e., > Grade 2 FL staining) tear film abnormalities in either group at the 12 month visit.

- **Keratometry (K) /Corneal topography**

  Corneal K values after 12 months of wearing orthokeratology contact lenses:

	OD		OS	
	Test	Control	Test	Control
Flat Corneal Value	41.33 ± 1.34 D	41.35 ± 1.38 D	41.45 ± 1.40 D	41.38 ± 1.31 D
Steep Corneal Value	42.47 ± 1.17 D	42.44 ± 1.44 D	42.73 ± 1.29 D	42.58 ± 1.38 D

  In the comparison of corneal topography parameters (corneal cylinder power / measurement of corneal astigmatism, corneal state, corneal thickness, corneal curvature, etc. of both eyes) of subjects after 1 day, 1 week, 2 weeks,

1 month, 3 months, 6 months, 9 months, and 12 months of wearing the orthokeratology contact lens, both groups maintained stable corneal cylinder measurements throughout the study and no clinical differences were found between the two groups.

- **Subjects' corneal thickness (CCT), corneal endothelial cell count, and changes after 30 days and 12 months of wearing the orthokeratology contact lens**

Corneal thickness

Corneal thickness of both eyes of subjects in the two groups were measured and compared after wearing the lenses for 1 month and 12 months.

	Corneal Thickness (mm)			
	Test (CCT in mm)		Control (CCT in mm)	
	OD	OS	OD	OS
Baseline	0.55 ± 0.04	0.55 ± 0.04	0.55 ± 0.03	0.55 ± 0.03
1 Month	0.55 ± 0.03	0.55 ± 0.03	0.54 ± 0.03	0.54 ± 0.03
12 Months	0.55 ± 0.03	0.55 ± 0.03	0.54 ± 0.03	0.54 ± 0.03

The results show that no significant differences are found between the two groups. The stability of corneal thickness measurements suggests that the overnight orthokeratology treatment did not adversely affect corneal structure or cause corneal edema during the study period.

Corneal endothelial cell density

Corneal endothelial cell density of subjects in the two groups were compared after wearing the lenses for 1 month and 12 months.

	Corneal endothelial cell count (/mm^2)			
	Test		Control	
	OD	OS	OD	OS
Baseline	2981.39 ± 296.91	3033.19 ± 331.46	2965.41 ± 351.97	3007.55 ± 343.09
1 Month	3015.27 ± 320.80	3072.64 ± 316.02	2990.19 ± 299.09	3037.17 ± 337.20
12 Months	2981.44 ± 349.41	3058.91 ±365.72	2958.72 ± 359.50	3034.69 ± 357.98

Compared to the baseline corneal endothelial cell density of both eyes of subjects during the screening period, results were similar between the two groups in corneal endothelial cell density changes after wearing the lenses for 1 month and 12 months, demonstrating that the lenses did not cause clinically significant endothelial cell loss, supporting their safety profile for overnight wear.

- **Changes in Best Corrected Visual Acuity (BCVA)**

  Proportion of total eyes whose BCVA decreased by 1 line, 2 lines or above in comparison to the baseline after 1-day, 1-week, 2-weeks, 30-days, 3-months, 6-months, 9-months and 12-months of treatment (presented in Snellen or Log MAR VA) are summarized below:

  Table 9 Decrease in BCVA

	BCVA Decrease by						**total number of eyes examined at follow-up**
	1 line		**2 lines**		**> 2 lines**		
	Test	**Control**	**Test**	**Control**	**Test**	**Control**	
1 Day	37 (7.4%)	42 (8.4%)	5 (1.0%)	3 (0.6%)	1 (0.2%)	0 (0%)	518
1 week	11 (2.2%)	20 (4.0%)	0 (0%)	5 (1.0%)	0 (0%)	1 (0.2%)	506
2 weeks	14 (2.8%)	23 (4.6%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	494
1 month	11 (2.2%)	26 (5.2%)	0 (0%)	4 (0.8%)	0 (0%)	0 (0%)	482
3 months	11 (2.2%)	12 (2.4%)	3 (0.6%)	1 (0.2%)	0 (0%)	1 (0.2%)	464
6 months	11 (2.2%)	8 (1.6%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	456
9 months	9 (1.8%)	10 (2.0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	442
12 months	17 (3.4%)	11 (2.2%)	3 (0.6%)	0 (0%)	1 (0.2%)	0 (0%)	430

Note: percentage = number of eyes with decreased vision/total number of eyes examined at follow-up.

For the 4 subjects (2 test and 2 control) with loss of >2 lines of Best Spectacle Corrected Visual Acuity (BSCVA) one corrected to 20/20 at study completion, one corrected to 20/20 before withdrawal from the study, one dropped out of the study with no follow-up recheck (20/63), and one showed loss of BSCVA at the completion of the study (20/50). The investigators reported that no complications, adverse events, or slit lamp abnormalities were associated with this issue at their final study visit.

- **Changes in Astigmatism**

  After 12 months of wear, cylinder power changes compared to baseline screening period values were as follows:

Right Eye

- Increase <1.00D: 99 subjects (100%) in test group and 97 subjects (97%) in the control group
- Increase 1.00D to 2.00D: 0 subjects in the test group and 3 subjects (3%) in the control group
- Increase >2.00D: 0 subjects in either group

Left Eye

- Increase <1.00D: 99 subjects (100%) in test group and 100 subjects (100%) in the control group
- Increase >1.00D: 0 subjects in either group

Results were similar between the two groups

The results show that orthokeratology treatment did not cause clinically significant increases in astigmatism. Subjects in both the test and control arms experienced minimal changes in cylinder power, indicating that the corneal reshaping was controlled and predictable without inducing any problematic astigmatism.

- **Intraocular Pressure (IOP)**
  Intraocular pressure was compared between the test and control groups after 1 month and 12 months of lens wear.

  At both 1 month and 12 months after wearing orthokeratology contact lenses, IOP measurements were similar between the test and control groups, with clinically insignificant changes reported.

- **Subjects adaptability after wearing Orthokeratology lenses**
  The fitting state of the lenses was evaluated at 1 day, 1 week, 2 weeks, 1 month, 3 months, 6 months, 9 months, and 12 months after initial wear. Evaluation of the fitting included lens centration, lens mobility, blinking pattern, and fluorescein staining pattern. Results were comparable between the two groups at all time points.

- **The damage rate, scratch, protein precipitation, etc. of lenses after 1-day, 1-week, 2-weeks, 30-days, 3-months, 6-months, 9-months and 12-months of treatment.**
  At each time point, both groups showed very few cases of lens damage, scratches, or protein deposits.

- **Study Discontinuations and clinical reason**
  Of the 280 subject enrolled in the study, 65 subjects dropped out. Of the 65 subjects, 16 followed the requirements of the study (per protocol set [PPS]) but their information was incomplete. The remaining 49 subjects did not

complete the trial according to the protocol. This included 10 subjects who completed all required visits but were excluded from the PPS data set.

Table 10 – Discontinued Subjects (by eyes)

DISCONTINUED EYES TABULATED BY COMPLETED VISITS AND REASONS FOR DISCONTINUATION WITH INCIDENCE RATES																
	Initial		**Month 1**		**Month 3**		**Month 6**		**Month 9**		**Month 12**		**Aggregated Discontinued**		**subtotal**	**Randomization Set N=560**
	C	**T**	**C**	**T**	**C**	**T**	**C**	**T**	**C**	**T**	**C**	**T**	**C**	**T**		**% Incidence**
1. Poor Scotopic Vision	0	0	0	2 (0.4%)	0	2 (0.4%)	0	0	0	0	0	0	0	4 (0.7%)	*4*	0.71%
2.Positive Slit Lamp Findings (SLF)	0	0	0	0	0	0	0	0	0	0	0	0	0	0	*0*	0.00%
3.Adverse Reaction	0	0	2 (0.4%)	0	0	2 (0.4%)	0	0	0	0	0	0	2 (0.4%)	2 (0.4%)	*4*	0.71%
4.Lens Position	0	0	0	0	0	0	0	0	0	0	0	0	0	0	*0*	0.00%
5.Discomfort	0	0	0	2 (0.4%)	0	0	0	2 (0.4%)	0	0	0	0	0	4 (0.7%)	*4*	0.71%
6.Handling Problems	4 (0.7%)	2 (0.4%)	2 (0.4%)	2 (0.4%)	0	0	0	0	0	0	0	0	6 (1.1%)	4 (0.7%)	*10*	1.79%
7.Disinterest	0	0	4 (0.7%)	0	0	0	0	0	0	0	2 (0.4%)	0	6 (1.1%)	0	*6*	1.07%
8.Lost to Follow-up	2 (0.4%)	0	4 (0.7%)	0	2 (0.4%)	2 (0.4%)	2 (0.4%)	0	6 (1.1)	4 (0.7%)	2 (0.4%)	4 (0.7%)	14 (2.5%)	10 (1.8%)	*28*	5.00%
9.None Given	8 (1.4%)	14 (2.5%)	6 (1.1%)	2 (0.4%)	4 (0.7%)	4 (0.7%)	4 (0.7%)	0	0	0	0	2 (0.4%)	26 (4.6%)	22 (3.9%)	*44*	7.86%
10.Other	4 (0.7%)	6 (1.1%)	4 (0.7%)	8 (1.4%)	2 (0.4%)	0	0	0	4 (0.7%)	0	0	2 (0.4%)	14 (2.5%)	16 (2.9%)	*30*	5.36%
(Other Specify)	4[a] (0.7%)	4[a] (0.7%) 2[b] (0.4%)	4[a] (0.7%)	8[a] (1.4%)	2[a] (0.4%)				4[a] (0.7%)			2[c] (0.4%)				
Subtotal	18 (3.2%)	22 (3.9%)	22 (3.9%)	16 (2.9%)	8 (1.4%)	10 (1.8%)	6 (1.1%)	2 (0.4%)	10 (1.8%)	4 (0.7%)	4 (0.7%)	8 (1.4%)	68 (12.1%)	62 (11.1%)	*130*	23.21%

percentage = n/N

[a] personal [b] exclusion [c] work related

At the time of database lock, of 280 patients enrolled in the PMA study, 215 patients (76.8%) are available for analysis at the completion of the study, the 12-month treatment visit. Three investigational sites enrolled subjects (140 subjects being classified into the test group and 140 subjects into the control group, respectively).

Among the subjects, 215 subjects completed all the follow-up visits required by the clinical trial—including 109 subjects from the test group and 106 subjects from the control group;

65 subjects discontinued the study (21 subjects dropped out directly because of their failure to obtain lenses; 10 subjects were eliminated. Subjects were classified into statistical analysis data sets upon the confirmation by principal

investigators, data administrators and statisticians from the clinical site. 252 subjects (124 from the test group, 128 from the control group) were classified into the FAS data set, 231 subjects (115 from the test group, 116 from the control group) were classified into the PPS data set, and 259 subjects (128 from the test group, 131 from the control group) were classified into the SS data set.

- **Lens/ Device Replacements**
  A total of 72 subjects experienced 85 instances of lens loss and broken lenses, including 30 subjects in the test group had 34 instances, and 42 subjects in the control group had 51 instances.

Adverse effects that occurred in the PMA clinical study:
There were no serious adverse events in the test group, and one person in the control group (0.76%) had one serious adverse event. It was determined that the adverse event was not related to the study device. Across the entire clinical trial, only two patients discontinued participation due to adverse events (AEs); no patients discontinued due to serious adverse events (SAEs).

Two treated eyes experienced a loss of best-corrected visual acuity (BSCVA) of greater than 2 lines, one treated eye had BSCVA worse than 20/40, and no treated eyes had an increase in corneal cylinder greater than 1.00 D. Among the four subjects across both study groups with loss of greater than 2 lines of BSCVA, one corrected to 20/20 at study completion, one corrected to 20/20 before study withdrawal, one discontinued without follow-up recheck after a recorded acuity of 20/63, and one had BSCVA of 20/50 at study completion. Investigators reported no associated complications, adverse events, or slit-lamp abnormalities at the final study visit.

The analysis results showed that there was no significant difference in the incidence of serious adverse events between the two groups.

2. **Primary Effectiveness Results**
The analysis of effectiveness was based on the 215 evaluable patients at the 12-month time point. Key effectiveness outcomes are presented in Table 15.

Primary Pre-Specified Effectiveness Endpoints:

1) **Uncorrected (distance) visual acuity (UCDVA) of subjects after 30 days of wearing the orthokeratology contact lens:**
Percentage of subjects whose UCDVA of both eyes reaches 20/25

In the comparison of uncorrected distance visual acuity (UCDVA) after 30 days of wearing the orthokeratology contact lens, the effectiveness rate of the test group was 84.68% (105 subjects), and the effectiveness rate of the control

group was 74.22% (95 subjects, P=0.046). The results show that statistical differences are found between the two groups, and the effectiveness rate in the test group was not inferior to that in the control group.

2) **Residual refractive error of subjects after 30 days of wearing the orthokeratology contact lens:**
Percentage of subjects whose residual spherical refractive error of both eyes is less than ±0.50D

In the comparison of the residual spherical refractive error after 1 month of wearing the orthokeratology contact lens, the effectiveness rate of the test group was 80.65% (100 subjects, and the effectiveness rate of the control group was 61.72% (79 subjects). The results show that the effectiveness in the test group was not inferior to that in the control group.

Compared with the refractive error at the screening period after wearing one month, the difference between test group and the control group was 2.41±0.96D, and the difference between the two groups was 2.07 ±1.00D. The refractive error of the test group decreased more than that of the control group. Compared to the refractive error at the screening period after wearing for 12 months, the changes in refractive error for the test group and the control group were 2.31± 1.10 D and 1.89 ±1.10, respectively.

Secondary Effectiveness Endpoints:

- **UCVA after 1-day, 1-week, 2-weeks, 30-days, 3-months, 6-months, 9-months and 12-months of treatment**

  In the FAS data set, the comparison of the UCVA of right and left eyes, between the two groups at 1 day, 1 week, 2 weeks, 1 month, 3 months, 6 months and 12 months after wearing orthokeratology contact lens showed clinically insignificant differences between the test and control groups.

  The Table 11 below shows the distribution of the UCDVA at the 12 month timepoint

- **Number/Percent of Eyes with UCDVA at least 20/20, 20/25, 20/32, 20/40 (or better) , etc. at 12 months (overall and stratified by baseline MRSE)**

Table 11 UCDVA stratified by pretreatment myopia (FAS 12 months)

UCDVA	Pretreatment Myopia (Spherical Diopters)													
	≤1.0 D		1.25 to 2.00 D		2.25 to 3.00 D		3.25 to 4.00 D		4.25 to 5.00 D		Not Report		Total	
	n/%		n/%		n/%		n/%		n/%		n/%		n/%	
	Test	Control	Test	Control	Test	Control	Test	Control	Test	Control	Test	Control	Test	Control
20/20 or better	4 (66.7%)	5 (71.4%)	25 (55.6%)	33 (52.4%)	49 (59.0%)	39 (39.8%)	49 (51.0%)	26 (34.7%)	0 (0%)	2 (40.0%)	8 (57.1%)	5 (62.5%)	135 (54.4%)	110 (43.0%)
20/25 or better	4 (66.7%)	5 (71.4%)	31 (68.9%)	37 (58.7%)	60 (72.3%)	57 (58.2%)	63 (65.6%)	38 (50.7%)	1 (25.0%)	3 (60.0%)	9 (64.3%)	6 (75.0%)	168 (67.7%)	146 (57.0%)
20/32 or better	4 (66.7%)	6 (85.7%)	34 (75.6%)	41 (65.1%)	62 (74.7%)	61 (62.2%)	69 (71.9%)	42 (56.0%)	1 (25.0%)	3 (60.0%)	10 (71.4%)	6 (75.0%)	180 (72.6%)	159 (62.1%)
20/40 or better	4 (66.7%)	6 (85.7%)	35 (77.8%)	44 (69.8%)	65 (78.3%)	67 (68.4%)	72 (75.0%)	45 (60.0%)	1 (25.0%)	3 (60.0%)	11 (78.6%)	6 (75.0%)	188 (75.8%)	171 (66.8%)
20/80 or better	5 (83.3%)	6 (85.7%)	35 (77.8%)	46 (73.0%)	67 (80.7%)	80 (81.6%)	76 (79.2%)	49 (65.3%)	1 (25.0%)	3 (60.0%)	12 (85.7%)	8 (100%)	196 (79.0%)	192 (75.0%)
20/200 or better	5 (83.3%)	7 (100%)	38 (84.4%)	50 (79.4%)	68 (81.9%)	84 (85.7%)	82 (85.4%)	52 (69.3%)	1 (25.0%)	3 (60.0%)	12 (85.7%)	8 (100%)	206 (83.1%)	204 (79.7%)
Not Report	1 (16.7%)	0 (0%)	7 (15.6%)	13 (20.6%)	15 (18.1%)	14 (14.3%)	14 (14.6%)	23 (30.7%)	3 (75.0%)	2 (40.0%)	2 (14.3%)	0 (0%)	42 (16.9%)	52 (20.3%)
Total eyes	6 (100%)	7 (100%)	45 (100%)	63 (100%)	83 (100%)	98 (100%)	96 (100%)	75 (100%)	4 (100%)	5 (100%)	14 (100%)	8 (100%)	248 (100.0%)	256 (100%)

Percentage = number of eyes with uncorrected distance visual acuity (UCDVA) within a specified range and within the myopia range, divided by the total number of eyes within the myopia range.

- **Refractive error (RE) after 1-day, 1-week, 2-weeks, 30-days, 3-months, 6-months, 9-months and 12-months of treatment.**

  Right Eye RE
  After 1 month of wearing the orthokeratology contact lens, mean RE in the right eyes was −0.36±0.66 D in the test group and −0.52±0.86 D in the control group. After 12 months, mean RE was −0.53±0.99 D in the test group and −0.65±0.93 D in the control group.

  Left Eye RE
  After 1 month of wearing the orthokeratology contact lens, mean RE in the left eyes was −0.33±0.67 D in the test group and −0.48±0.85 D in the control group. After 12 months, mean RE was −0.44±0.83 D in the control group and −0.61±0.79 D in the control group.

  The collective results show clinically insignificant differences between the test and control groups.

- **The corneal keratometry (K) value of subjects after 1 day, 1 week, 2 weeks, 30 days, 3 months, 6 months, 9 months and 12 months of treatment:**

In the FAS sets, the steep K values (D) and flat K values (D) at 1 day, 1 week, 2 weeks, 1 month, 3 months, 6 months, 9 months and 12 months show clinically insignificant differences between the test and control orthokeratology contact lens.

Right eye's flat corneal K value
In the FAS and PPS sets, in the comparison of the flat K value of cornea of right eyes of subjects in the two groups after wearing the lenses for 1 day, 1 week, 2 weeks, 1 month, 3 months, 6 months, 9 months and 12 months, there was no clinically significant differences between the two groups: After 12 months of wear, the K values of subjects in the test group and in the control group respectively reached 41.33±1.34D and 41.35±1.38D (FAS).

Right eye's steep corneal K value
In the FAS and PPS sets, in the comparison of the steep K value of cornea of right eyes of subjects in the two groups after wearing the lenses for 1 day, 1 week, 2 weeks, 1 month, 3 months, 6 months, 9 months and 12 months, there was no clinically significant differences between the two groups. After 12 months of wear, the K values of subjects in the test group and in the control group respectively reached 42.47±1.17D and 42.44±1.44D (FAS).

Left eye's flat corneal K value
In the FAS and PPS sets, in the comparison of the flat K value of cornea of left eyes of subjects in the two groups after wearing the lenses for 1 day, 1 week, 2 weeks, 1 month, 3 months, 6 months, 9 months and 12 months, there was no clinically significant differences between the two groups. After 12 months of wear , the K values of subjects in the test group and in the control group respectively reached 41.45±1.40D and 41.38±1.31D (FAS)

Left eye's steep corneal K value
In the FAS and PPS sets, in the comparison of the steep K value of cornea of left eyes of subjects in the two groups after wearing the lenses for 1 day, 1 week, 2 weeks, 1 month, 3 months, 6 months, 9 months and 12 months, there was no clinically significant differences between the two groups. After 12 months of wear , the K values of subjects in the test group and in the control group respectively reached 42.73±1.29D and 42.58±1.38D. (FAS)

Other Important Effectiveness Outcomes/Analyses Provided

The following additional data were also evaluated to establish the effectiveness of the device:

- **Mean reduction in magnitude of MRSE from baseline to 12 month (all eyes) - overall and stratified by baseline MRSE**

Table 12 Refractive Change from Baseline Visit (FAS 12 months vs. baseline)

	Pretreatment Myopia (MRSE)													
	≤1.0 D		1.25 to 2.00 D		2.25 to 3.00 D		3.25 to 4.00 D		4.25 to 5.00 D		Not Report		Totals	
Refractive Change	n/%		n/%		n/%		n/%		n/%		n/%		n/%	
	Test	Control	Test	Control	Test	Control	Test	Control	Test	Control	Test	Control	Test	Control
0.00	0 (0.0%)	0 (0.0%)	1 (0.9%)	2 (1.9%)	3 (1.7%)	3 (1.7%)	2 (1.2%)	2 (1.2%)	0 (0%)	0 (0%)	0 (0.00%)	0(0.00%)	6 (1.2%)	7 (1.4%)
Decreases														
＜0.12	1 (7.7%)	0 (0%)	1 (0.9%)	0 (0%)	0 (0%)	1 (0.6%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	2 (0.4%)	1 (0.2%)
0.12 to 0.50	2 (15.4%)	2 (15.4%)	6 (5.6%)	3 (2.8%)	10 (5.5%)	7 (3.9%)	10 (5.9%)	3 (1.8%)	0 (0.0%)	0 (0.0%)	2 (9.1%)	3 (13.6%)	30 (6.0%)	18 (3.6%)
0.5 to 0.62	0 (0.0%)	0 (0%)	0 (0.00%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
0.62 to 1.00	2 (15.4%)	4 (30.8%)	7 (6.5%)	13 (12.0%)	4 (2.2%)	5 (2.8%)	9 (5.3%)	2 (1.2%)	0 (0.0%)	1 (11.1%)	3 (13.6%)	3 (13.6%)	25 (5.0%)	28 (5.6%)
1.00 to 1.12	0 (0%)	0 (0%)	0 (0.0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
1.12 to 1.50	0 (0.0%)	0 (0%)	7 (6.5%)	12 (11.1%)	15 (8.3%)	12 (6.6%)	4 (2.48%)	7 (4.1%)	0 (0.0%)	0 (0.0%)	3 (13.6%)	0 (0.0%)	29 (5.8%)	31 (6.2%)
1.50 to 1.62	0 (0.0%)	0 (0%)	0(0.00%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
1.62 to 2.00	0 (0.0%)	0 (0%)	4 (3.7%)	7 (6.5%)	13 (7.2%)	14 (7.7%)	3 (1.8)	4 (2.3%)	0 (0%)	0 (0%)	3 (13.6%)	0 (0%)	23 (4.6%)	25 (5.0%)
＞2.00	0 (0.0%)	0 (0%)	0 (0%)	0 (0%)	11 (6.1%)	28 (15.5%)	39 (22.8%)	26 (15.2%)	0 (0.0%)	2 (22.2%)	1 (4.6%)	2 (9.1%)	51 (10.1%)	58 (11.5%)
Not Report	1 (7.7%)	0 (0%)	15 (13.4%)	18 (16.7%)	23 (12.7%)	23 (12.7%)	21 (12.3%)	31 (18.1%)	4 (44.4%)	2 (22.2%)	2 (9.1%)	0 (0%)	66 (13.1%)	74 (14.7%)
Totals	6 (46.1%)	6 (46.2%)	40 (37.0%)	53 (49.1%)	76 (42.0%)	90 (49.7%)	86 (50.3%)	73 (42.7%)	4 (44.4%)	5 (55.6%)	14 (63.6%)	8 (36.4%)	226 (44.8%)	235 (46.6%)
Increase														
＜0.12	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
0.12 to 0.50	0 (0%)	0 (0%)	3 (2.8%)	7 (6.5%)	1 (0.6%)	1 (0.6%)	4 (2.3%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	8 (1.6%)	8 (1.6%)
0.5 to 0.62	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
0.62 to 1.00	0 (0%)	0 (0%)	0 (0%)	1 (0.9%)	0 (0%)	3 (1.7%)	3 (1.8%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	3 (0.6%)	4 (0.8%)
1.00 to 1.12	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
1.12 to 1.50	0 (0%)	0 (0%)	1 (0.9%)	0 (0%)	1 (0.6%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	2 (0.4%)	0 (0%)
1.50 to 1.62	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
1.62 to 2.00	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (0.6%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (0.2%)	0 (0%)
＞2.00	0 (0%)	1 (7.7%)	0 (0%)	0 (0%)	1 (0.6%)	1 (0.6%)	1 (0.6%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	2 (0.4%)	2 (0.4%)
Not Report	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Totals	0 (0%)	1 (7.7%)	4 (3.7%)	8 (7.4%)	4 (2.2%)	5 (2.8%)	8 (4.7%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	16 (3.2%)	14 (2.8%)

Percentage = number of eyes within the refractive change range and within the myopia range, divided by the total number of eyes within the myopia range.

- **A level of attempted versus achieved reduction in manifest refractive error (the proportions of subjects within ±0.50, ±1.00, and ±2.00 of the targeted amount of correction for the follow-up intervals from the time-point of stability out to the end of the study)**

Table 13 Percent of eyes at 12 months that are within ±0.50, ±1.00, ±2.00, and ±3.00 of MRSE target

Criteria	1 Months		3 Months		6 Months		9 Months		12 Months	
	Test	Control	Test	Control	Test	Control	Test	Control	Test	Control
n	248	256	248	256	248	256	248	256	248	256
MRSE change ±0.50 D	91 (36.7%)	94 (36.7%)	83 (33.5%)	91 (35.6%)	76 (30.7%)	93 (36.3%)	54 (21.8%)	83 (32.4%)	45 (18.2%)	77 (30.1%)
± 1.00 D	143 (57.7%)	162 (63.3%)	125 (50.4%)	131 (51.2%)	121 (48.8%)	135 (52.7%)	104 (41.9%)	136 (53.1%)	80 (32.3%)	117 (45.7%)
± 2.00 D	197 (79.4%)	209 (81.6%)	186 (75.0%)	190 (74.2%)	186 (75.0%)	181 (70.7%)	164 (66.1%)	178 (69.5%)	148 (59.7%)	175 (68.4%)
± 3.00 D	214 (86.3%)	222 (86.7%)	208 (83.9%)	206 (80.5%)	203 (81.9%)	198 (77.3%)	186 (75.0%)	194 (75.8%)	186 (75.0%)	196 (76.6%)

- **Change in spherical refraction between 9-12 months**

Table 14 Stability of manifest refraction stratified by dioptric group (FAS)

	9 and 12 Months n/N (%)											
Change in Spherical Diopters	≤1.0 D		1.25 to 2.00 D		2.25 to 3.00 D		3.25 to 4.00 D		4.25 to 5.00 D		Not Report	
	n/N (%)		n/N (%)		n/N (%)		n/N (%)		n/N (%)		n/N (%)	
	Test	Control	Test	Control	Test	Control	Test	Control	Test	Control	Test	Control
≤1.0 D	5 (38.5%)	7 (53.9%)	34 (31.5%)	47 (43.5%)	58 (32.0%)	69 (38.1%)	69 (40.4%)	43 (25.2%)	0 (0.0%)	2 (22.2%)	6 (27.3%)	8 (36.4%)
1.00 to 1.50 D	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (1.9%)	4 (2.2%)	7 (3.9%)	3 (1.8%)	2 (1.2%)	1 (11.1%)	1 (11.1%)	0 (0.0%)	0 (0.0%)
1.50 to 2.00 D	0 (0.0%)	0 (0.0%)	1 (0.93%)	0 (0.0%)	2 (1.1%)	4 (2.2%)	1 (0.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (4.6%)	0 (0.0%)
2.00 to 2.50 D	0 (0.0%)	0 (0.0%)	1 (0..93%)	0 (0.0%)	0 (0.0%)	2 (1.1%)	2 (1.2%)	1 (0.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
2.50 to 3.00 D	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
3.00 D	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.9%)	1 (0.6%)	0 (0.0%)	0 (0.0%)	1 (0.6%)	0 (0.0%)	0 (0.0%)	1 (4.6%)	0 (0.0%)
Not Report	1 (7.7%)	0 (0.0%)	9 (8.3%)	13 (12.0%)	18 (9.9%)	15 (8.3%)	21 (12.3%)	28 (16.4%)	3 (33.3%)	2 (22.2%)	6 (27.3%)	0 (0.0%)
Totals	6 (46.2%)	7 (54.8%)	45 (41.7%)	63 (58.3%)	83 (45.9%)	98 (54.1%)	96 (56.1%)	75 (43.9%)	4 (44.4%)	5 (55.6%)	14 (63.6%)	8 (36.4%)
Mean Difference	-0.29	-0.29	-0.24	-0.11	-0.27	-0.08	-0.43	-0.01	0.75	0.25	0.13	-0.82
SD	0.39	0.99	0.80	0.92	1.19	1.10	1.35	1.10	0.00	0.28	1.63	0.71
95% CI	(-0.71, 0.53)	(-2.53, 1.85)	(-0.63, 0.16)	(-0.50, 0.25)	(-0.70, 0.15)	(-0.39, 0.30)	(-0.88, 0.01)	(-0.49, 0.46)	(.,.)	(-0.43, 0.93)	(-2.46, 2.71)	(-1.93, 0.31)

Note that for n/N(%), n = number of eyes with both baseline manifest refractive range and change in spherical diopter range, and N = total number of eyes within baseline manifest refractive range.

This table presents the changes in spherical diopter values among patients in the FAS dataset from the 9th to the 12th month of follow-up. The column headers are stratified according to baseline manifest refraction results, while the row headers indicate the magnitude of spherical diopter changes.

SUMMARY TABLE OF KEY SAFETY AND EFFECTIVENESS VARIABLES from PRIMARY CLINICAL STUDY

There is no significant difference in UCVA, dioptric values , corneal topography values and key effectiveness evaluations between the test group and the control group at any time point in the study; there is no significant difference in corneal fluorescein staining examination, corneal topographic parameters, cylindrical values , BSCVA, intra-ocular pressure (IOP), corneal health , adaptability, contact lens evaluation, complications, adverse events and serious adverse events and other key safety indices between test group and control group after wearing the lenses .

Table 15 Summary of Key Safety & Effectiveness Variables (N=Eyes)

Criteria	1 Month		3 Months		6 Months		9 Months		12 Months	
	Test	Control	Test	Control	Test	Control	Test	Control	Test	Control
n	248	256	248	256	248	256	248	256	248	256
UCVA 20/20 or better	164 (66.13%)	133 (51.95%)	162 (65.32%)	125 (48.83%)	172 (69.35%)	136 (53.13%)	146 (58.87%)	133 (51.95%)	135 (54.44%)	110 (42.97%)
UCVA 20/40 or better	218 (87.90%)	211 (82.42%)	208 (83.87%)	188 (73.44%)	206 (83.06%)	196 (76.56%)	192 (77.42%)	181 (70.70%)	188 (75.81%)	171 (66.80%)
The number of eyes in different spherical diopter range										
±0.50 D	91 (36.69%)	94 (36.72%)	83 (33.47%)	91 (35.55%)	76 (30.65%)	93 (36.33%)	54 (21.77%)	83 (32.42%)	45 (18.15%)	77 (30.08%)
± 1.00 D	143 (57.66%)	162 (63.28%)	125 (50.40%)	131 (51.17%)	121 (48.79%)	135 (52.73%)	104 (41.94%)	136 (53.13%)	80 (32.26%)	117 (45.70%)
± 2.00 D	196 (79.03%)	209 (81.64%)	186 (75.00%)	190 (74.22%)	186 (75.00%)	181 (70.70%)	164 (66.13%)	178 (69.53%)	148 (59.68%)	175 (68.36%)
± 3.00 D	214 (86.29%)	222 (86.72%)	208 (83.87%)	206 (80.47%)	203 (81.85%)	198 (77.34%)	186 (75.00%)	194 (75.78%)	186 (75.00%)	196 (76.56%)
Change in spherical diopters	**Baseline-1month – Mean Dif (SD)**		**Month 1 – 3 Mean Dif (SD)**		**Month3 – 6 Mean Dif (SD)**		**Month6 – 9 Mean Dif(SD)**		**Month9 – 12 Mean Dif (SD)**	
0.12 to 1D	1.12 (0.34) n=6	0.93 (0.54) n=7	0.00 (0.28) n=6	-0.31 (0.56) n=7	-0.15 (0.38) n=6	0.14 (1.14) n=7	-0.15 (0.26) n=6	-0.22 (0.59) n=7	-0.29 (0.52) n=6	-0.29 (0.92) n=7
1.25 to 2.00D	1.10 (0.85) n=45	1.23 (0.60) n=63	-0.03 (0.69) n=45	-0.11 (0.66) n=63	-0.01 (0.84) n=45	-0.05 (0.72) n=63	-0.18 (0.51) n=45	-0.23 (0.84) n=63	-0.24 (0.80) n=45	-0.11 (0.96) n=63

2.25 to 3.00D	1.74 (1.10) n=83	1.89 (1.21) n=98	-0.20 (1.42) n=83	0.00 (1.20) n=98	-0.11 (0.97) n=83	-0.06 (1.12) n=98	-0.03 (0.82) n=83	-0.09 (1.09) n=98	-0.27 (1.19) n=83	-0.04 (1.10) n=98
3.25 to 4.00D	2.59 (1.54) n=96	2.46 (1.24) n=75	-0.17 (1.69) n=96	-0.26 (1.54) n=75	0.06 (1.13) n=96	-0.12 (1.33) n=75	-0.32 (0.76) n=96	0.03 (1.36) n=75	-0.43 (1.35) n=96	-0.01 (1.08) n=75
>4.0D	0.00 (0) n=5	3.80 (1.17) n=7	-0.85 (0.40) n=5	-0.38 (0.08) n=7	-1.06 (0.80) n=5	2.13 (0.08） n=7	-0.56 (0) n=5	-0.32 (0.11) n=7	1.13 (0) n=5	0.30 (0.33) n=7

	Treat, n=248	Control, n=256
Serious Adverse Event* **	0	2
Loss of BSCVA > 2 lines* **	2	2
BSCVA worse than 20/40* **	1	1
Increase of> 1 D Coreal Cyl* **	0	3

NOTE : ***The description of these events occurred during the entire trial. Since the numbers are small, they are not tabulated across time.

This table corresponds to the FAS data set.
The UCVA rows represent the number of eyes that attained an uncorrected visual acuity (UCVA) of 20/20 or better and 20/40 or better at various follow-up time points.
The percentages in parentheses represent the proportion of the number of eyes in this group to the total number of eyes in the test and control groups within the FAS data set.

The MRSE change (from baseline) (±0.50D, ±1.00D, ±2.00D, ±3.00) rows represent the number of eyes with spherical refractive error changes of 0.50D or less, 1.00D or less, 2.00D or less, and 3.00D or less at different follow-up time points.

The MRSE changes in refractive ranges represent the different groups based on the distinct refraction results at baseline. The horizontal data represent the mean and standard deviation of spherical diopter changes in eyes during different follow-up periods.
"n" represents the number of data.

Regarding the 4 subjects with loss of ≥2 lines of BSCVA, see discussion above under “Changes in Best Corrected Visual Acuity (BCVA).”

3. Subgroup Analyses

Descriptive subgroup analyses were conducted for different age groups and study sites for the two primary endpoints. The results supported the conclusion that the test treatment is non-inferior to the control treatment across all 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

The Financial Disclosure by Clinical Investigators regulation (21 CFR 54) requires applicants who submit a marketing application to include certain information concerning the compensation to, and financial interests and arrangement of, any clinical investigator conducting clinical studies covered by the regulation. The pivotal clinical study included 32 investigators. None of the clinical investigators had disclosable financial interests/arrangements as defined in sections 54.2(a), (b), (c), and (f). The information provided does not raise any questions about the reliability of the data.

XII. SUMMARY OF SUPPLEMENTAL CLINICAL INFORMATION TO ASSESSS SAFETY ENDPOINTS IN ADDITIONAL SUBJECTS

The applicant supplemented the results of their submitted primary clinical study (that included 215 completed subjects) with additional clinical data (290 completed subjects) to support PMA approval of the subject lens.

Based on the current version of ISO 11980 (Ophthalmic optics – Contact lenses and contact lens care products – Requirements and guidance for clinical investigations, Annex A), an adequately powered study consisting of a minimum sample size of 300 completed subjects (after accounting for the 25% dropout rate) for a duration of 12 months was needed to ensure that the safety of the subject device was adequately assessed.

As such, in addition to the primary pivotal study (summarized in Section X above) for the Dilight™ (roflufocon E) Overnight Lens, the Applicant provided clinical safety data that included 290 total subjects (144 Test:146 Control) who were treated with an overnight orthokeratology contact lenses worn by the test group, who completed the 12 month visit.

The study was conducted outside the United States (OUS) according to Good Clinical Practice regulations in China,

Summary of the Supplemental roflufocon E overnight orthokeratology study:

Shenzhen New industry Ophthalmic new technology Co., LTD. sponsored a multicenter, randomized, positive-controlled trial with **330 subjects** led by the Eye Hospital of Wenzhou Medical University.

The study was conducted at **5 hospitals** located in **China.**

The test lens was an overnight orthokeratology rigid gas permeable contact lens produced by Shenzhen New industry Ophthalmic new technology Co., LTD, manufactured from roflufocon E contact lens blanks supplied by Contamac Ltd.

The control lens was the Euclid orthokeratology lens manufactured by Euclid Systems Corporation from **oprifocon A** lens blanks.

A total of 360 subjects were screened, and 330 (91.7%) were randomized on a 1:1 basis, with 166 in the test group and 164 in the control group. One hundred forty-four (144) subjects in the test group and 146 subjects in the control group completed the study.

Forty subjects (12.1%, including subjects with no treatment) dropped out of the study early, including 22 in the treatment group and 18 in the control group.

The average age of the subjects was 12.9 years old (test group: 13.1 years; control group: 12.8 years). One hundred and eighty (180) female subjects received treatment (test group: 95; control group: 85) and 140 male subjects received treatment (test group: 65; control group: 75).

The objective of the study was to evaluate the effectiveness and safety of the test lens for the temporary reduction of myopic refractive error from -1.00D ~ -4.00D (including -1.00D and -4.00D). The safety and effectiveness endpoints were tested for noninferiority between the test and control groups. However, only the safety endpoints were evaluated for approvability of the current PMA.

The Safety Endpoints from the Supplemental Study are listed below:

Safety Endpoints

1) The incidence and number of (serious) adverse events, device-related (serious) adverse events, and device defects in both groups during the study period;

2) Subjects' BCVA at 1 day, 1 week, 2 weeks, 30 days, 3 months, 6 months, 9 months, 12 months after wearing lenses, and the percentage of subjects with 1, 2 or more lines of BCVA loss at each visit point compared to the baseline BCVA;

3) Corneal curvature and K1, K2 (steep and flat meridians) and corneal astigmatism of corneal topography are measured at 1 day, 1 week, 2 weeks, 30 days, 3 months, 6 months, 9 months, and 12 months after wearing lenses;

4) The subjects' cylinder power at 1 day, 1 week, 2 weeks, 30 days, 3 months, 6 months, 9 months and 12 months after wearing the lenses, and the ratio of the increase of cylindrical power at each visit compared with the baseline cylinder power of 1.00D or less, 1.00 D to 2.00 D or more than 2.00D;

5) Fundus examination, central corneal thickness measurement and corneal endothelial cell count are performed at 6 and 12 months after wearing lenses;

6) Changes in intraocular pressure at 6 and 12 months after wearing lenses compared with baseline;

7) At each follow-up visit (1 day, 1 week, 2 weeks, 30 days, 3 months, 6 months, 9 months, 12 months) after wearing the Orthokeratology lenses, the following parameters were assessed:
   - fitting status
   - lens condition assessment
   - subject's perception score while wearing the lenses

8) The breakage rate, scratches and protein deposition of the lenses recorded at 1 day, 1 week, 2 weeks, 30 days, 3 months, 6 months, 9 months and 12 months after wearing the lenses;

In this supplemental study, the incidence rates of device-related AEs were similar in the test group and the control groups and were within the range reported in the literature, with no serious complications related to wearing orthokeratology lenses observed.

XIII. 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 (ODP), an FDA advisory committee, for review and recommendation because the information in the PMA substantially duplicates information previously reviewed by this panel.

XIV. CONCLUSIONS DRAWN FROM PRECLINICAL AND CLINICAL STUDIES

A. Effectiveness Conclusions

Clinical performance data demonstrated the effectiveness rate of UCVA and residual refractive error of subjects wearing Dilight™ (roflufocon E) Overnight Orthokeratology Contact Lenses was non-inferior compared with the currently marketed control lens. There are no significant differences in the effectiveness evaluation for UCVA, refractive error, and corneal K value at all time points for the test and control groups; therefore, the primary endpoint for the study were met. The nonclinical studies confirmed that the lens properties are consistent with currently marketed rigid gas permeable contact lenses and the lenses are consistently manufactured within tolerance of the design specifications.

B. Safety Conclusions

The risks of the device are based on nonclinical laboratory, as well as data collected in clinical studies conducted to support PMA approval as described above.

Clinical performance data from both the Primary and Supplementary Study demonstrated no significant differences between the test and control groups with regards to the tear film evaluation, fluorescein imaging examination, corneal topography parameters, BCVA, UCVA, IOP, corneal endothelial cell count, adaptability, lens evaluation, complications, adverse events and serious adverse events. No unexpected safety findings were observed.

The combined data shows adequate device safety**,** with similar safety and risk profiles to analogous approved devices.

C. Benefit-Risk Determination

The probable benefits of the Dilight™ (roflufocon E) Overnight Orthokeratology Contact Lenses are based on data collected in a clinical study conducted to support PMA approval. In the clinical study, after 12 months of overnight wear uncorrected distance visual acuity was 20/40 or better in 75.8% of subjects wearing the DilightTM (roflufocon E) Overnight Orthokeratology Contact Lens. This study has demonstrated clinically meaningful results with the Dilight™ (roflufocon E) Overnight Orthokeratology Contact Lens showing noninferiority to the control device for all safety and effectiveness endpoints.

The probable risks of the device are also based on data collected in the primary clinical study as well as the supplementary study conducted to support PMA approval. No unexpected safety findings were observed. Adverse event rates were consistent with the currently marketed control device and did not raise new safety concerns for the Dilight™ (roflufocon E) Overnight Orthokeratology Contact Lenses.

1. Patient Perspective

   This submission 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 from the Primary pivotal Clinical Study and supplemental clinical data supports that the probable benefits of the Dilight™ (roflufocon E) Overnight Orthokeratology Contact Lenses outweigh the probable risks for the temporary reduction of myopic refractive error.

D. Overall Conclusions

The results of the preclinical testing, primary clinical and supplementary studies provide reasonable assurance of the safety and effectiveness of the Dilight™ (roflufocon E) Overnight Orthokeratology Contact Lens for the study population, refractive conditions and specified wearing modality when used as indicated in accordance with the directions for use.

Key endpoints related to the effectiveness rate of UCVA and residual refractive error were met, as well as the secondary endpoints. Adverse event rates were consistent with

the currently marketed control device. The collective clinical (pivotal and supplemental studies) and nonclinical studies presented in this PMA demonstrate the safety and effectiveness of the Dilight^{TM} (roflufocon E) Overnight Orthokeratology Contact Lens for the temporary reduction of myopic refractive error.

XV. CDRH DECISION

CDRH issued an approval order on 8/5/2026.

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

XVI. 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.

XVII. REFERENCES

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

International Standard Organization 10993-10, Biological Evaluation of Medical Devices – Part 10: Tests for irritation and skin sensitization

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 9394, Ophthalmic optics – Contact lenses and contact lens care products – Determination of biocompatibility by ocular study with rabbit eyes

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

International Standard Organization 11980, Ophthalmic optics – Contact lenses and contact lens care products – Guidance for clinical investigations

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

Guidance for Premarket Submissions of Orthokeratology Rigid Gas Permeable Contact Lenses

N. Tahhan; F. Sarfraz; N. Raad; C. Raad; T. Weber; R. Du Toit; E. Papas; Orthokeratology and the Eyelid Investigative Ophthalmology & Visual Science May 2003, Vol.44, 3714.