510 (k) SUMMARY OF SAFETY AND EFFECTIVENESS

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is: K183200

I. SUBMITTER

Date Prepared: November 15th, 2018

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II. DEVICE

Trade Name: **iSee (roflufocon D, roflufocon E) Daily Wear Orthokeratology Contact Lenses**

Common Name: Daily wear rigid gas permeable (hydrophobic) contact lens (Orthokeratology)

Classification Name: Rigid gas permeable contact lens. (21 CFR 886.5916)

Regulatory Class: Class II

Product Code: MUW

III. PREDICATE DEVICE

The **iSee (roflufocon D, roflufocon E) Daily Wear Orthokeratology Contact Lenses** are substantially equivalent to the following predicate devices:

- "OPTIMUM GP OK Daily Wear Contact Lens (Roflufocon D & E)"
  By Contamac, Ltd.
  510(k) number; **K160859**

IV. DEVICE DESCRIPTION

The **iSee (roflufocon D, roflufocon E) Daily Wear Orthokeratology Contact Lenses** are are lathe cut from one of the following hydrophobic, FDA Group #3 fluoro-silicone acrylate materials: roflufocon D or roflufocon E—with the following properties:

	ROFLUFOCON D	ROFLUFOCON E
Refractive Index	1.4333	1.4332
Light Transmission (clear)	>97%	>97%
Light Transmission (tinted)	>90%	>90%
Wetting Angle (Dynamic contact receding angle)	3°	6°
Specific Gravity	1.166	1.155
Oxygen Permeability (Dk) ISO/FATT Method	100×10^{-11} (cm^2/sec) (ml O_2/ml x mm Hg @ 35°C)	125×10^{-11} (cm^2/sec) (ml O_2/ml x mm Hg @ 35°C)
Visitint lenses contain one or more of the following color additives conforming to: 21 CFR Part 73 & 74, Subpart D	D & C Green No. 6, FD & C Red No. 17, CI Solvent Yellow 18	D & C Green No. 6, FD & C Red No. 17, CI Solvent Yellow 18

The **iSee (roflufocon D, roflufocon E) Daily Wear Orthokeratology Contact Lenses** are available in the following lens parameters:

Parameter	Range	Tolerance
Base Curve	6.50mm to 11.00mm	± 0.05 mm
Center Thickness	0.10mm to 0.70mm	± 0.02 mm
Diameter	6.50mm to 11.50mm	± 0.10mm
Spherical Power	-10.00 D to +3.00 D (in 0.25D steps)	± 0.12 (0 to </= 5D) ± 0.18 (5 to </= 10.0D) ± 0.25 (10 to </= 15D) ± 0.37 (15 to </= 20D) ± 0.50 (over 20D)

Secondary Curves	0.10mm to 2.00mm (flatter or steeper than base curve)	± 0.10mm
Peripheral Curves	0.10mm to 2.00mm (flatter or steeper than base curve)	± 0.10mm
Multifocal Power	+1.00 D to 3.75 D (in 0.25 D steps)	± 0.25D

V. INDICATIONS FOR USE

The **iSee (roflufocon D, roflufocon E) Daily Wear Orthokeratology Contact Lenses** are indicated for daily wear in an orthokeratology fitting program for the temporary reduction of myopia of up to 5.00 diopters in non-diseased eyes. To maintain the orthokeratology effect of myopia reduction, lens wear must be continued on a prescribed wearing schedule.

Eyecare practitioners may prescribe the lenses for frequent/planned replacement wear, with cleaning, disinfection and scheduled replacement. When prescribed for frequent/planned replacement wear, the lens may be cleaned and disinfected using a chemical (not heat) lens care system.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH PREDICATE DEVICE

The following matrix illustrates the production method, intended use and materials of **iSee (roflufocon D, roflufocon E) Daily Wear Orthokeratology Contact Lenses**, as well as the predicate device.

	iSee Daily OK Contact Lens	**Optimum GP OK Contact Lens**
	Subject Device	**Predicate Device (K160859)**
Classification	Same as predicate	Class II Lenses, Rigid Gas Permeable, Daily Wear 21 CFR 886.5916
Product Code	Same as predicate	MUW
FDA Group #	Same as predicate	Group # 3 Fluoro Silicone Acrylate
USAN	Same as predicate	Roflufocon D, Roflufocon E
Production Method	Same as predicate	Lathe-Cut
Actions	Same as predicate	The contact lenses act as a refractive medium that focus light rays from near and distant objects on the retina. (orthokeratology)
Intended Use	Same as predicate	Daily Wear (orthokeratology)
Indication for Use	Same as predicate	Indicated for daily wear in an orthokeratology fitting program for the temporary reduction of myopia of up to 5.00 diopters in non-diseased eyes.

VII. PERFORMANCE DATA

~ Non-Clinical Studies ~

The non-clinical performance data to establish the safety and effectiveness of contact lenses manufactured from roflufocon D and roflufocon E has been addressed by reference to the predicate devices.

~ Clinical Studies ~

Clinical performance data to demonstrate the safety and effectiveness of contact lenses manufactured from roflufocon D and roflufocon E have been addressed in previous applications.

VIII. CONCLUSIONS

Substantial Equivalence

Information presented in this Premarket Notification establishes that **iSee (roflufocon D, roflufocon E) Daily Wear Orthokeratology Contact Lenses** are as safe and effective as the predicate device when used in accordance with the labeled directions for use and for the proposed indication.

Risks and Benefits

The risks of the subject device are the same as those normally attributed to the wearing of rigid gas permeable (RGP) daily wear contact lenses. The benefits to the patient are the same as those for other RGP contact lenses.