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.

510(k) number: **K171077**

Applicant information:

Date Prepared:	June 27th, 2017
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Device Information:

Device Classification:	Class II
Product Code:	HQD; MUW
Classification Name:	Daily Wear Rigid Gas Permeable Contact Lens (21 CFR 886.5916)
Trade Name:	**HEXA100 (hexafocon A) Daily Wear Contact Lens**

Purpose of 510(k) Submission: **~ New Device ~**

Predicate Devices:

The **HEXA100 (hexafocon A) Daily Wear Contact Lenses** are substantially equivalent to the following predicate devices:

"Boston XO (hexafocon A) Daily Wear Contact Lens" -primary predicate
By Bausch & Lomb, Inc.

510(k) number; **K071043**

"OPTIMUM GP OK (Orthokeratology) Daily Wear Contact Lens (roflufocon D & E)"
by Contamac Ltd.
510(k) number; **K160859**

"**Optimum GP with HPT (roflufocon C, D, and E) Daily Wear Contact Lenses**"
by Contamac Ltd.
510(k) number; **K161100**

Device Description:

The **HEXA100 (hexafocon A) Daily Wear Contact Lens** is manufactured from a machine latheable rigid gas permeable material composed of siloxanyl fluoromethacrylate copolymer that is tinted for visibility and available with or without an ultraviolet (UV) light absorber.

In the **HEXA100 (hexafocon A) Daily Wear Contact Lens** with UV Blocker, a Benzophenone UV blocking monomer is used to block UV radiation. The UV blocking for HEXA100 averages > 98% in the UVB range of 280nm – 315nm and >84% in the UVA range of 316 – 380nm.

The **HEXA100 (hexafocon A) Daily Wear Contact Lens** incorporates a visibility tint to make the lens more visible for handling. The tinted lenses contain one or more of the following color additives: D&C Green No. 6, C.I. Solvent Yellow No. 18, D&C Violet No. 2 and D&C Red No. 17.

The **HEXA100 (hexafocon A) Daily Wear Contact Lens** may be prescribed in a daily wear orthokeratology fitting program for the temporary reduction of myopia of up to 5.00 diopters in non-diseased eyes.

The **HEXA100 (hexafocon A) Daily Wear Contact Lens** may be optionally treated to incorporate Tangible™ Hydra-PEG—which is a thin polyethylene glycol (PEG)-based polymer that is covalently bonded to the surface of the contact lens and is designed to enhance the surface properties of the contact lens while retaining the mechanical properties of the underlying material. When treated with Tangible™ Hydra-PEG, the underlying material (hexafocon A) is encapsulated in a thin layer of polymer that results in measurable improvement of wettability (sessile drop contact angle) compared to untreated lenses. The resulting layer is hydrophilic and approximately 30nm in thickness. The following table depicts the contact angle of the coated vs. uncoated **HEXA100 (hexafocon A) Daily Wear Contact Lenses**:

	HEXA 100 - Hexafocon A	
	Uncoated*	**Tangible™ Hydra-PEG Coated***
Average Sessile Drop Contact Angle (degrees) n=30	96.4°	49.1°
Standard Deviation	2.79	5.81
% Standard Deviation	2.90	11.82

*lenses were manufactured and soaked in borate buffered saline for 24 hours prior to contact angle measurement

The **HEXA100 (hexafocon A) Daily Wear Contact Lenses** may be packaged and shipped "dry" or

"wet" in a polypropylene contact lens case. The primary container for shipping the **HEXA100 (hexafocon A) Daily Wear Contact Lenses** is the PolyVial Contact Lens Case. When shipped "wet", the **HEXA100 (hexafocon A) Daily Wear Contact Lenses** may be packaged and shipped in the Unique pH contact lens care system by Menicon Co., Ltd**.** The active ingredients in Unique pH solution are Edetate Disodium 0.01% and Polyquaternium 10.0011%.

The physical properties of the **HEXA100 (hexafocon A) Daily Wear Contact Lenses** are as follows:

	HEXA100 (hexafocon A)	**HEXA100 (hexafocon A) with Tangible™ Hydra-PEG**
Refractive Index (dry)	1.4136	1.4134
Light Transmission (@380-780nm)	>91%	>94%
UVA Transmission (@316-380nm)	<16%	<16%
UVB Transmission (@280-315nm)	<2%	<2%
Specific Gravity (g/cm^3)	1.266	1.266
Oxygen Permeability (Dk) ISO/FATT Method	113×10^{-11} (cm^2/sec) (ml O_2/ml x mm Hg @ 35°C)	118×10^{-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, C.I. Solvent Yellow No. 18, D&C Violet No. 2 and D&C Red No. 17	D&C Green No. 6, C.I. Solvent Yellow No. 18, D&C Violet No. 2 and D&C Red No. 17

The **HEXA100 (hexafocon A) Daily Wear Contact Lens** is available in the Spherical, Toric, Multifocal/Bifocal, Irregular Cornea (Scleral) design configurations, within the following lens parameters:

- Chord Diameter: 7.0mm to 22.0mm
- Center Thickness: Varies
- Base Curve: 5.0mm to 8.0mm
- Spherical Powers: -20.00 Diopters to +20.00 Diopters
- Toric Powers: up to -10.00 Diopters
- Add Powers: up to +4.00 Diopters

The **HEXA100 (hexafocon A) Daily Wear Contact Lens** for daily wear orthokeratology is available in following lens parameters:

- Chord Diameter: 6.5 to 11.5 mm
- Center Thickness: 0.10 to 0.70 mm
- Base Curve (BC): 6.5 to 11.0 mm
- Secondary Curves: 0.10 to 2.0 mm (flatter or steeper than BC)
- Peripheral Curves: 0.10 to 2.0 mm (flatter or steeper than BC)
- Spherical Powers: -10.00 to +3.00 D

Intended Use:

The **HEXA100 (hexafocon A) SPHERICAL** Rigid Gas Permeable (RGP) Contact Lens is indicated for daily wear for the correction of refractive error in aphakic and not aphakic persons with non-diseased eyes with myopia or hyperopia.

The **HEXA100 (hexafocon A) TORIC** Rigid Gas Permeable (RGP) Contact Lens is indicated for daily wear for the correction of refractive error in aphakic and not aphakic persons with non-diseased eyes with myopia or hyperopia and/or possesses refractive astigmatism not exceeding 10.00 diopters.

The **HEXA100 (hexafocon A) MULTIFOCAL/BIFOCAL** Rigid Gas Permeable (RGP) Contact Lens is indicated for daily wear for the correction of refractive error in aphakic and not aphakic persons with non-diseased eyes with myopia or hyperopia and/or possesses refractive astigmatism not exceeding 4 diopters and are presbyopic requiring add power of up to +4.00 diopters.

The **HEXA100 (hexafocon A) IRREGULAR CORNEA** Daily Wear Contact Lens may be prescribed in otherwise non-diseased eyes that require a rigid gas permeable lens for the management of irregular corneal conditions such as; keratoconus, pellucid marginal degeneration or following penetrating keratoplasty or refractive (e.g. LASIK) surgery.

The **HEXA100 (hexafocon A) 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.

Testing:

Non-clinical Testing

A series of in vitro and in vivo preclinical toxicology and biocompatibility tests were performed to assess the safety and effectiveness of the **HEXA100 (hexafocon A) Daily Wear Contact Lens**. All non-clinical toxicology tests were conducted in accordance with the GLP regulation. All other testing was conducted according to valid scientific protocols. Test results of the non-clinical testing on the **HEXA100 (hexafocon A) Daily Wear Contact Lens** demonstrate that:

- The finished lenses (uncoated and coated with Tangible™ Hydra-PEG) are not toxic and not irritating,
- The physicochemical, mechanical, and optical properties of the Tangible™ Hydra-PEG coated and uncoated lenses are substantially equivalent to the predicate device.
- Bioburden levels are below the acceptance criteria (<100 cfu/lens) initially (dry) and following 30 days of storage in Unique pH at ambient temperatures,

- Physical parameters are stable following 30 days of storage in Menicon Unique pH at ambient temperatures, and
- The Tangible™ HydraPEG coated Hexafocon A lenses are physically compatible with currently marketed care solutions.

Clinical Testing — The clinical safety and effectiveness has been previously established for contact lenses manufactured from (hexafocon A) and contact lenses coated with Tangible™ Hydra-PEG.

Conclusions Drawn from Studies

Validity of Scientific Data

Laboratories under Good Laboratory Practice regulations conducted toxicology, microbiology, and shelf-life stability studies following scientific protocols. The data were determined to be scientifically valid under 21 CFR 860.7

Substantial Equivalence

Information presented in this Premarket Notification establishes that the **HEXA100 (hexafocon A) Daily Wear Contact Lens** is 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.

Substantial Equivalence:

The **HEXA100 (hexafocon A) Daily Wear Contact Lens** is substantially equivalent to the Boston XO (hexafocon A) Daily Wear Contact Lens (cleared under K071043) in terms of the following:

- contact lens material (hexafocon A)
- production method: lathe cut manufacturing process
- functionality
- indications for use (sphere, toric, multifocal, irregular cornea)

The **HEXA100 (hexafocon A) Daily Wear Contact Lens** is substantially equivalent to the OPTIMUM GP OK (Orthokeratology) Daily Wear Contact Lens (roflufocon D & E) (cleared under K160859) in terms of the following:

- indications for use (daily wear orthokeratology)
- orthokeratology lens design

The **HEXA100 (hexafocon A) Daily Wear Contact Lens** is substantially equivalent to the Optimum

GP with HPT (roflufocon C, D, and E) Daily Wear Contact Lens (cleared under K161100) in terms of the following:

- may incorporate the Tangible™ Hydra-PEG surface coating

The following matrix illustrates the production method, lens function and material characteristics of the **HEXA100 (hexafocon A) Daily Wear Contact Lens** as well as the predicate devices.

Substantial Equivalence Matrix

	HEXA100 (hexafocon A) New Device	**Boston XO (hexafocon A) Predicate Device**	**Optimum GP with HPT (roflufocon C, D, E) Predicate Device**	**OPTIMUM GP OK (Orthokeratology) (roflufocon D & E) Predicate Device**

Intended Use	Indicated for daily wear for the correction of visual acuity in aphakic and not aphakic persons with non-diseased eyes with myopia or hyperopia and/or presbyopia. The lens may also be prescribed for management of irregular corneal conditions such as keratoconus and post graft fitting. 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.	Indicated for daily wear for the correction of visual acuity in aphakic and not aphakic persons with non-diseased eyes with myopia or hyperopia and/or presbyopia. The lens may also be prescribed for management of irregular corneal conditions such as keratoconus and post graft fitting.	Indicated for daily wear for the correction of visual acuity in aphakic and not aphakic persons with non-diseased eyes with myopia or hyperopia and/or presbyopia. The lens may also be prescribed for management of irregular corneal conditions such as keratoconus and post graft fitting.	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.
Functionality	The contact lenses act as a refractive medium that focus light rays from near and distant objects on the retina	The contact lenses act as a refractive medium that focus light rays from near and distant objects on the retina	The contact lenses act as a refractive medium that focus light rays from near and distant objects on the retina	The contact lenses act as a refractive medium that focus light rays from near and distant objects on the retina
Indications	Daily Wear	Daily Wear	Daily Wear	Daily Wear
Production Method	Lathe-Cut, custom manufactured	Lathe-Cut, custom manufactured	Lathe-Cut, custom manufactured	Lathe-Cut, custom manufactured
USAN name	hexafocon A	hexafocon A	roflufocon C, D, E	roflufocon D, E
Water Content (%)	<1%	<1%	<1%	<1%
Specific Gravity	1.266	1.265	Roflufocon C: 1.178 Roflufocon D: 1.166 Roflufocon E: 1.155	Roflufocon D: 1.166 Roflufocon E: 1.155
Oxygen Permeability (cm^2/sec) (ml O_2/ml x mm Hg @ 35°C)	Uncoated: 113 x 10^{-11} Hydra-PEG Coated: 118 x 10^{-11}	108 x 10^{-11}	Roflufocon C: 65x10^{-11} Roflufocon D: 100x10^{-11} Roflufocon E: 125x10^{-11}	Roflufocon D: 100x10^{-11} Roflufocon E: 125x10^{-11}
Wettability (sessile drop contact angle)	Hydra-PEG Coated: 49.1° Uncoated: 96.4°	96.4°	Roflufocon C: 40.28° Roflufocon D: 40.40° Roflufocon E: 36.90° (measured by captive bubble)	Roflufocon D: 93.28° Roflufocon E: 93.64° (measured by captive bubble)
UV Absorber/Blocker Available	Yes, Optional	Yes	Yes, Optional	Yes, Optional
Includes Hydra-PEG Surface Coating	Yes, Optional	No	Yes	No