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: K182304

I. SUBMITTER

Date Prepared: October 24th, 2018

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II. DEVICE

Trade Name: **Hyper GP (tisilfocon A) Daily Wear Contact Lens**

Common Name: Daily wear rigid gas permeable contact lens

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

Regulatory Class: Class II

Product Code: HQD; MUW

III. PREDICATE DEVICE

The **Hyper GP (tisilfocon A) Daily Wear Contact Lens** is substantially equivalent to the following predicate devices:

- "Rigid Gas Permeable Contact Lenses (tisilfocon A)"
  By Menicon Co., Ltd.
  510(k) number; **K103561**
- "OPTIMUM GP OK 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**

IV. DEVICE DESCRIPTION

The **Hyper GP (tisilfocon 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. The lenses may be plasma treated during the manufacturing process.

In the **Hyper GP (tisilfocon A) Daily Wear Contact Lens** with UV Blocker, a Benzophenone UV blocking monomer is used to block >99% of UV radiation in the UVB range (280nm – 315nm) and >85% in the UVA range (316 – 380nm).

The **Hyper GP (tisilfocon 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 **Hyper GP (tisilfocon 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 **Hyper GP (tisilfocon 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 (tisilfocon 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 lenses:

	Hyper GP tisilfocon A	
	Uncoated	**Tangible™ Hydra-PEG Coated**
Average Sessile Drop Contact Angle (degrees) n=30	106.2	37.34
Standard Deviation	5.31	5.30

The **Hyper GP (tisilfocon A) Daily Wear Contact Lens** may be packaged and shipped "dry" or "wet" in a polypropylene contact lens case. The primary container for shipping the **Hyper GP (tisilfocon A) Daily Wear Contact Lens** is the PolyVial Contact Lens Case. When shipped "wet", the **Hyper GP (tisilfocon A) Daily Wear Contact Lens** 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 **Hyper GP (tisilfocon A) Daily Wear Contact Lens** is as follows:

	Hyper GP (tisilfocon A)	**Hyper GP (tisilfocon A) with Tangible™ Hydra-PEG**
Refractive Index (dry)	1.4378	1.4398
Light Transmission (@380-780nm)	91.694	93.427
UVA Transmission (@316-380nm)	14.241	16.105
UVB Transmission (@280-315nm)	0.011	0.020
Oxygen Permeability (Dk) ISO/FATT Method	180×10^{-11} (cm^2/sec) (ml O_2/ml x mm Hg @ 35^oC)	180×10^{-11} (cm^2/sec) (ml O_2/ml x mm Hg @ 35^oC)
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 **Hyper GP (tisilfocon A) Daily Wear Contact Lens** is available in the Spherical, Toric, Multifocal/Bifocal, Irregular Cornea (Scleral) design configurations, within the following lens parameters:

Parameter	**Range**	**Tolerance**
Base Curve	4.00mm to 12.00mm	± 0.05 mm
Center Thickness	Varies	± 0.02 mm
Chord Diameter	7.00mm to 22.00mm	± 0.10mm
Spherical Power	-30.00 D to +30.00 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)
Cylindrical Power	Up to -10.00 D (in 0.25 D steps)	± 0.25 (0 to </= 2D) ± 0.37 (2 to </= 4D) ± 0.50 (over 4D)
Cylindrical Axis	1° to 180° (in 1° steps)	± 5°
Multifocal Power	+1.00 D to 4.00 D (in 0.25 D steps)	± 0.25D

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

Parameter	Range	Tolerance
Base Curve (BC)	4.0mm to 12.00mm	± 0.05 mm
Center Thickness	0.10mm to 0.70mm	± 0.02 mm
Diameter	6.50mm to 11.50mm	± 0.10mm
Secondary Curves	0.10mm to 2.00mm (flatter or steeper than BC)	± 0.10mm
Peripheral Curves	0.10mm to 2.00mm (flatter or steeper than BC)	± 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)

V. INDICATIONS FOR USE

The **Hyper GP (tisilfocon 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 **Hyper GP (tisilfocon 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 **Hyper GP (tisilfocon 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 **Hyper GP (tisilfocon 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 **Hyper GP (tisilfocon 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.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH PREDICATE DEVICE

The **Hyper GP (tisilfocon A) Daily Wear Contact Lens** is substantially equivalent to the Rigid Gas Permeable Contact Lenses (tisilfocon A) (cleared under K103561) in terms of the following:

- Intended use – daily wear contact lenses
- Indications for use
- Actions
- USAN – contact lens material composition
- Classification – Lenses, Rigid Gas Permeable, Daily Wear (21 CFR 886.5916)
- FDA material group – group # 3 fluoro silicone acrylate
- Production method – lathe cut

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

- Intended use – daily wear contact lenses
- Indications for use – daily wear orthokeratology
- Contact lens design – orthokeratology
- Actions
- Classification – Lenses, Rigid Gas Permeable, Daily Wear (21 CFR 886.5916)
- FDA material group – group # 3 fluoro silicone acrylate
- Production method – lathe cut

The **Hyper GP (tisilfocon A) Daily Wear Contact Lens** is substantially equivalent to the Optimum GP with HPT (roflufocon C, D, and E) Daily Wear Contact Lenses (cleared under K161100) in terms of the following:

- Intended use – daily wear contact lenses
- May be surface coated with Tangible Hydra-PEG
- Actions
- Classification – Lenses, Rigid Gas Permeable, Daily Wear (21 CFR 886.5916)
- FDA material group – group # 3 fluoro silicone acrylate
- Production method – lathe cut

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

Substantial Equivalence Matrix

	Hyper GP (tisilfocon A) New Device	**Menicon (tisilfocon 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 refractive error (myopia, hyperopia, presbyopia and/or astigmatism) in aphakic and non-aphakic persons with non-diseased eyes. The lenses may be prescribed for daily wear in otherwise non-diseased eyes that require a rigid contact lens for the management of irregular corneal conditions such as keratoconus, pellucid marginal degeneration, or following penetrating keratoplasty or refractive (e.g., LASIK) surgery.	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	tisilfocon A	tisilfocon A	roflufocon C, D, E	roflufocon D, E
Water Content (%)	<1%	<1%	<1%	<1%
Specific Gravity	1.20	1.20	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)	180 $x10^{-11}$	160 $x10^{-11}$	Roflufocon C: $65x10^{-11}$ Roflufocon D: $100x10^{-11}$ Roflufocon E: $125x10^{-11}$	Roflufocon D: $100x10^{-11}$ Roflufocon E: $125x10^{-11}$
UV Blocker	Yes, Optional	Yes	Yes, Optional	Yes, Optional
Plasma Treatment	Yes, Optional	Yes	Yes, Optional	Yes, Optional
Hydra-PEG Surface Coating	Yes, Optional	No	Yes, Optional	No

VII. PERFORMANCE DATA

~ Non-Clinical Studies ~

A series of in vitro and in vivo preclinical toxicology and biocompatibility tests were performed to assess the safety and effectiveness of the **Hyper GP (tisilfocon 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 **Hyper GP (tisilfocon 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 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 tisilfocon A lenses are physically compatible with currently marketed care solutions.

~ Clinical Studies ~

Clinical performance data to demonstrate the safety and effectiveness of contact lenses manufactured from tisilfocon A has been previously addressed.

VIII. CONCLUSIONS

Substantial Equivalence

Information presented in this Premarket Notification establishes that **Hyper GP (tisilfocon A) Daily Wear 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.