



March 27, 2026

Zhuhai Fitlens Medical Technology Co., Ltd.  
% Bret Andre  
Principal Consultant  
Andre Vision and Device Research  
6119 Canter Lane  
West Linn, OR 97068

Re: K253822

Trade/Device Name: GPA (hexafocon A) Rigid Gas Permeable Contact Lenses

Regulation Number: 21 CFR 886.5916

Regulation Name: Rigid Gas Permeable Contact Lens

Regulatory Class: Class II

Product Code: HQD

Dated: November 21, 2025

Received: February 27, 2026

Dear Bret Andre:

We have reviewed your section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (the Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm> identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (<https://www.fda.gov/media/99812/download>) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (<https://www.fda.gov/media/99785/download>).

Your device is also subject to, among other requirements, the Quality Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13484 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see <https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products>); good manufacturing practice requirements as set forth in the Quality Management System Regulation (QMSR) (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at <https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system>.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems>.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (<https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance>) and CDRH Learn (<https://www.fda.gov/training-and-continuing-education/cdrh-learn>). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic.

See the DICE website (<https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice>) for more information or contact DICE by email ([DICE@fda.hhs.gov](mailto:DICE@fda.hhs.gov)) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

J Angelo Green -S

J. Angelo Green, Ph.D.

Assistant Director

DHT1A: Division of Ophthalmic Devices

OHT1: Office of Ophthalmic, Anesthesia,  
Respiratory, ENT, and Dental Devices

Office of Product Evaluation and Quality

Center for Devices and Radiological Health

Enclosure

## Indications for Use

Submission Number (if known)

K253822

Device Name

GPA (hexafocon A) Rigid Gas Permeable Contact Lenses

Indications for Use (Describe)

The GPA (hexafocon A) Rigid Gas Permeable 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 0.75 diopters.

The GPA-AT (hexafocon A) Rigid Gas Permeable 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 6.00 diopters.

The GPA-M, GPA-PN and GPA-PD (hexafocon A) Rigid Gas Permeable Contact Lenses are 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 0.75 diopters.

The GPA-PDT, GPA-MT, and GPA-PNT (hexafocon A) Rigid Gas Permeable Contact Lenses are 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 6.00 diopters and are presbyopic requiring add power of up to +4.00 diopters.

The GPA-K (hexafocon A) Rigid Gas Permeable 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.

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.

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

**CONTINUE ON A SEPARATE PAGE IF NEEDED.**

# 510 (k) SUMMARY

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: K253822**

## **I. SUBMITTER**

Date Prepared: November 21, 2025

Name: **Zhuhai Fitlens Medical Technology Co., Ltd.**

Address: Building 6, No. 129, Dingxing Road, Tangjiawan Town, High-tech Zone,  
Zhuhai, Guangdong, 519080, P.R. China

Contact Person: Grace Wang  
Regulatory Director

Phone number: 0756-3380040

Consultant: Bret Andre  
Andre Vision and Device Research  
6119 Canter Ln.  
West Linn, OR 97068

Phone number: (503) 372-5226

## **II. DEVICE**

Trade Name: **GPA (hexafocon A) Rigid Gas Permeable Contact Lenses**

Common  
Name: Rigid gas permeable contact lens

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

Regulatory  
Class: Class II

Product Code: HQD

**~Reason for Submission~**

*New Device*

### III. PREDICATE DEVICE

The GPA (hexafocon A) Rigid Gas Permeable Lenses for daily wear are substantially equivalent to the following predicate devices:

- “RIGID GAS PERMEABLE CONTACT LENS”  
By POLYMER TECHNOLOGY  
510(k) number; **K000795**  
Product Code: HQD
- “Boston XO® (hexafocon A) and Boston XO2® (hexafocon B) Rigid Gas Permeable Contact Lens”  
By Bausch + Lomb Inc.  
510(k) number; **K171404**  
Product Code: HQD

### IV. DEVICE DESCRIPTION

The GPA (hexafocon A) Rigid Gas Permeable Contact Lenses are lathe manufactured from the lens blank material hexafocon A, which is blue-tinted for visibility and may include an ultraviolet (UV) light absorber. The contact lens material name hexafocon A has been adopted by the United States Adopted Names (USAN) Council.

The GPA (hexafocon A) Rigid Gas Permeable Contact Lenses are a family of rigid gas permeable contact lenses available in the following design configurations:

Model	Description
GPA-A	Rigid gas permeable contact lens with double aspherical design on both the front and back surfaces.
GPA-K	Rigid gas permeable contact lens with double aspherical design on both the front and back surfaces, specifically designed for keratoconus.
GPA-M	Progressive multifocal rigid gas permeable contact lens with double aspherical design on both the front and back surfaces.
GPA-PN	Multifocal rigid gas permeable contact lens with an aspherical back surface and a concentric multi-zone front surface where the center zone is for near vision, specifically designed for presbyopia correction.
GPA-PD	Multi-focal rigid gas permeable contact lens with an aspherical back surface and a concentric multi-zone front surface where the center zone is for distance vision, specifically designed for presbyopia correction.
GPA-AT	Rigid gas permeable contact lens with double toric design on both the front and back surfaces.
GPA-MT	Progressive multifocal rigid gas permeable contact lens with a toric back surface and an aspherical front surface.
GPA-PNT	Multifocal rigid gas permeable contact lens with a toric back surface and a concentric multi-zone front surface where the center zone is for near vision, specifically designed for correcting presbyopia in patients with large corneal astigmatism.
GPA-PDT	Multi-focal rigid gas permeable contact lens with an aspherical back surface and a concentric multi-zone front surface where the center zone is for distance vision, specifically designed for correcting presbyopia in patients with large corneal astigmatism.

The GPA (hexafocon A) Rigid Gas Permeable Contact Lenses are in the following lens parameters:

Parameter	Abbr.	Range (mm)					Step (mm)	Tolerance
		GPA-A	GPA-K	GPA-M	GPA-PN	GPA-PD		
BC radius /mm	BC	6.50~9.50	4.50~7.50	6.50~9.50	6.50~9.50	6.50~9.50	0.05	± 0.05 mm
Total diameter /mm	TD	8.50~11.50	7.00~11.00	8.00~12.00	8.00~12.00	8.00~12.00	0.10	± 0.10mm
Spherical power /D	SPH	-20.00~+20.00	-20.00~+20.00	-20.00~0.00	-20.00~+6.00	-20.00~+6.00	0.25	± 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)
Additional power /D	Add	N/A	N/A	-5.00~+5.00	0~+4.00	0~+4.00	0.25	± 0.38D
Center thickness /mm	CT	0.11~0.60	0.11~0.60	0.11~0.60	0.11~0.60	0.11~0.60	-	± 0.02 mm
Optional back toric design	-	GPA-AT	N/A	GPA-MT	GPA-PNT	GPA-PDT	-	-
Optional back toric diopters /D	TOR	0.00~6.00	N/A	0.00~6.00	0.00~6.00	0.00~6.00	0.25	± 0.25 (0 to <= 2D) ± 0.37 (2 to <= 4D) ± 0.50 (over 4D)
Surface Appearance	-	Lenses should be clear with no surface defect						

The physical properties of the GPA (hexafocon A) Rigid Gas Permeable Contact Lenses are as follows:

Hexafocon A Rigid Gas Permeable Contact Lens	
Refractive Index	1.415
Modulus (MPa)	1269
Hardness (Shore D)	81
Specific Gravity	1.27
Oxygen Permeability (Dk)	$100 \times 10^{-11}$ (cm <sup>2</sup> /sec) (ml O <sub>2</sub> /ml x mm Hg @ 35°C)
Color Additive(s)	D&C Green #6

GPA (hexafocon A) Rigid Gas Permeable Contact Lenses are distributed in a dry state, without immersion in solution. The primary packaging consists of a polycarbonate plastic screw-top vial equipped with a lens clamp to secure the product during transit. All accompanying documentation—including the case, packing slip, and invoice—identifies lens specifications: base curve, dioptric power, cylindrical power, cylindrical axis, additional power, diameter, central thickness, color, and lot number.

## V. INDICATIONS FOR USE

The **GPA** (hexafocon A) Rigid Gas Permeable 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 0.75 diopters.

The **GPA-AT** (hexafocon A) Rigid Gas Permeable 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 6.00 diopters.

The **GPA-M**, **GPA-PN** and **GPA-PD** (hexafocon A) Rigid Gas Permeable Contact Lenses are 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 0.75 diopters.

The **GPA-PDT**, **GPA-MT**, and **GPA-PNT** (hexafocon A) Rigid Gas Permeable Contact Lenses are 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 6.00 diopters and are presbyopic requiring add power of up to +4.00 diopters.

The **GPA-K** (hexafocon A) Rigid Gas Permeable 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.

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 GPA (hexafocon A) Rigid Gas Permeable Contact Lenses are substantially equivalent to the predicate device (cleared under K000795) in terms of the following:

- Intended use – daily wear contact lenses
- Indication for use – refractive correction
- Classification – Lenses, Rigid Gas Permeable, Daily Wear (21 CFR 886.5916)
- FDA material group – group # 3 fluoro silicone acrylate
- USAN material (hexafocon A)
- Production method – lathe cut

The GPA (hexafocon A) Rigid Gas Permeable Contact Lenses are substantially equivalent to the predicate device (cleared under K171404) in terms of the following:

- Intended use – daily wear contact lenses
- Indication for use – refractive correction & therapeutic use (irregular cornea)
- Classification – Lenses, Rigid Gas Permeable, Daily Wear (21 CFR 886.5916)
- FDA material group – group # 3 fluoro silicone acrylate
- USAN material (hexafocon A)
- Production method – lathe cut

The following matrix illustrates the production method, lens function and material characteristics of the GPA (hexafocon A) Rigid Gas Permeable Contact Lenses, as well as the predicate devices.

	<b>GPA (hexafocon A) Rigid Gas Permeable Contact Lenses</b>	<b>Rigid Gas Permeable Contact Lens</b>	<b>Boston XO® (hexafocon A) and Boston XO2® (hexafocon B) Rigid Gas Permeable Contact Lens</b>
	<b>Subject Device</b>	<b>Predicate Device (K000795)</b>	<b>Predicate Device (K171404)</b>
<b>Classification</b>	Class II Lenses, Rigid Gas Permeable, Daily Wear 21 CFR 886.5916	Class II Lenses, Rigid Gas Permeable, Daily Wear 21 CFR 886.5916	Class II Lenses, Rigid Gas Permeable, Daily Wear 21 CFR 886.5916
<b>Product Code</b>	HQD	HQD	HQD
<b>FDA Group #</b>	Group # 3 Fluoro Silicone Acrylate	Group # 3 Fluoro Silicone Acrylate	Group # 3 Fluoro Silicone Acrylate
<b>Material (USAN)</b>	hexafocon A	hexafocon A	hexafocon A; hexafocon B
<b>Production Method</b>	Lathe-Cut	Lathe-Cut	Lathe-Cut
<b>Intended Use</b>	Daily Wear	Daily Wear	Daily Wear
<b>Water Content (%)</b>	<1%	<1%	<1%
<b>UV Absorber Available</b>	Yes	Yes	Yes

	<b>Indications for Use</b>
<b>GPA and GPK Rigid Gas Permeable Contact Lenses (subject device)</b>	<p>The <b>GPA</b> (hexafocon A) Rigid Gas Permeable 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 0.75 diopters.</p> <p>The <b>GPA-AT</b> (hexafocon A) Rigid Gas Permeable 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 6.00 diopters.</p> <p>The <b>GPA-M, GPA-PN and GPA-PD</b> (hexafocon A) Rigid Gas Permeable Contact Lenses are 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 0.75 diopters.</p> <p>The <b>GPA-PDT, GPA-MT, and GPA-PNT</b> (hexafocon A) Rigid Gas Permeable Contact Lenses are 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 6.00 diopters and are presbyopic requiring add power of up to +4.00 diopters.</p> <p>The <b>GPA-K</b> (hexafocon A) Rigid Gas Permeable 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.</p> <p>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.</p>

<p><b>Rigid Gas Permeable Contact Lens Predicate Device (K000795)</b></p>	<p>The BOSTON XO contact lens material is indicated for daily wear for the correction of refractive ametropia (myopia, hyperopia, astigmatism and presbyopia) in aphakic and not-aphakic persons with non-diseased eyes. The lens may be disinfected using a chemical disinfection system only.</p>
<p><b>Boston XO® (hexafocon A) and Boston XO2® (hexafocon B) Rigid Gas Permeable Contact Lens Predicate Device (K171404)</b></p>	<p>BOSTON XO® (hexafocon A) Contact Lenses are indicated for daily wear for the correction of refractive ametropia (myopia, hyperopia, astigmatism and presbyopia) in aphakic and non aphakic persons with non-diseased eyes. Also, the lenses may be prescribed 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).</p> <p>Furthermore, eyes suffering from certain ocular surface disorders may benefit from the physical protection, aqueous hydrated environment and the saline bath provided by scleral lens designs. Boston XO Scleral Lens designs for daily wear are indicated for therapeutic use for the management of irregular and distorted corneal surfaces where the subject:</p> <ol style="list-style-type: none"> <li>1. cannot be adequately corrected with spectacle lenses</li> <li>2. requires a rigid gas permeable contact lens surface to improve vision</li> <li>3. is unable to wear a corneal rigid gas permeable lens due to corneal distortion or surface irregularities</li> </ol> <p>Common causes of corneal distortion include but are not limited to corneal infections, trauma, tractions as a result of scar formation secondary to refractive surgery (e.g. LASIK or radial keratotomy) or corneal transplantation. Causes may also include corneal degeneration (e.g. keratoconus, keratoglobus, pellucid marginal degeneration, Salzmann's nodular degeneration) and corneal dystrophy (e.g., lattice dystrophy, granular corneal dystrophy, Reis-Bucklers dystrophy, Cogan's dystrophy).</p> <p>The Boston XO Scleral Lens designs for daily wear are also indicated for therapeutic use in eyes with ocular surface disease (e.g. ocular Graft-versus-Host disease, Sjögren's syndrome, dry eye syndrome and Filamentary Keratitis), limbal stem cell deficiency (e.g. Stevens-Johnson syndrome, chemical radiation and thermal burns), disorders of the skin (e.g. atopy, ectodermal dysplasia), neurotrophic keratitis (e.g. Herpes simplex, Herpes zoster, Familial Dysautonomia), and corneal exposure (e.g. anatomic, paralytic) that might benefit from the presence of an expanded tear reservoir and protection against an adverse environment. When prescribed for therapeutic use for a distorted cornea or ocular surface disease, the Boston Scleral Lenses may concurrently provide correction of refractive error. The lenses may be disinfected using a chemical disinfection (not heat) system only.</p>

## VII. PERFORMANCE DATA

### ~ Non-Clinical Studies ~

Non-clinical testing to demonstrate the safety and effectiveness of contact lenses manufactured from hexafocon A has been addressed by reference to previous 510(k) clearances.

Additionally, the following testing was performed on finished GPA (hexafocon A) Rigid Gas Permeable Contact Lenses:

*Bench Testing*—manufacturing verification testing was conducted to demonstrate the ability of Zhuhai Fitlens Medical Technology Co., Ltd. to manufacture lenses, on a repeatable basis, from hexafocon A supplied lens blanks to a variety of prescribed parameters. All lenses were manufactured to established finished product specifications within the ANSI Z80.20 tolerance.

*Bioburden Testing*—bioburden testing conducted on hexafocon A rigid gas permeable lenses manufactured at Zhuhai Fitlens Medical Technology Co., Ltd. demonstrated that the colony forming units (CFU) per lens was within the established acceptance criteria of less

than 100 CFU per lens.

Biocompatibility Testing—biocompatibility studies were conducted on finished gas permeable contact lenses produced at the Zhuhai Fitlens Medical Technology Co., Ltd. facility. The following biocompatibility/toxicology tests were conducted in accordance with Good Laboratory Practice (GLP):

- In-Vitro Cytotoxicity: Cytotoxicity testing was performed in accordance with ISO 10993-5 with results indicating that extracts from finished lenses are not cytotoxic.
- Systemic Toxicity: The finished lenses meet the requirements of the systemic injection test in accordance with ISO 10993-11, and extracts from finished lenses did not induce acute systemic toxicity.
- Acute Ocular Irritation: Acute ocular irritation testing was performed in accordance with ISO 10993-23, and extracts from finished lenses did not induce ocular irritation.

~ *Clinical Studies* ~

Finished contact lenses manufactured from hexafocon A were previously cleared by the United States Food and Drug Administration (FDA). Based on recommendations in the FDA guidance titled *Class II Daily Wear Contact Lenses - Premarket Notification [510(k)] Guidance Document*, clinical studies are not required for this 510(k) premarket notification.

## VIII. CONCLUSIONS

### Validity of Scientific Data

Laboratories under Good Laboratory Practice regulations conducted biocompatibility 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 GPA (hexafocon A) Rigid Gas Permeable Contact Lenses for daily wear are as safe and effective as the predicate devices when used in accordance with the labeled directions for use and for the proposed indications.

### Risks and Benefits

The risks of the GPA (hexafocon A) Rigid Gas Permeable Contact Lenses 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.