October 22, 2024

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

Re: K241398
Trade/Device Name: SDJMASTERVISION (fluoroxyfocon 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: May 3, 2024
Received: September 20, 2024

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 titled "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 System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 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 systems (QS) regulation (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.

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) 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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K241398

Device Name

SDJMASTERVISION (fluoroxyfocon A) Rigid Gas Permeable Contact Lenses

Indications for Use *(Describe)*

The SDJMASTERVISION (fluoroxyfocon A) Rigid Gas Permeable Contact Lenses are 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.

The SDJMASTERVISION (fluoroxyfocon A) Rigid Gas Permeable Contact Lenses 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 lens may concurrently provide correction of refractive error.

The SDJMASTERVISION (fluoroxyfocon A) Rigid Gas Permeable Contact Lenses 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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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: K241398

I. SUBMITTER

Date Prepared: October 17, 2024

Name: **Tianjin MasterVision Technology Co., Ltd.**
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Consultant: Bret Andre
Andre Vision and Device Research
6119 Canter Ln.
West Linn, OR 97068
Phone number: (503) 372-5226

II. DEVICE

Trade Name: **SDJMASTERVISION (fluoroxyfocon 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 SDJMASTERVISION (fluoroxyfocon A) Rigid Gas Permeable Contact Lenses for daily wear are substantially equivalent to the following predicate devices:

- "Acuity 200™ (fluoroxyfocon A), Acuity 100™ (hexafocon A), Acuity 200™ with Tangible® Hydra-PEG® (fluoroxyfocon A), and Acuity 100™ with Tangible® Hydra-PEG® Rigid Gas Permeable Contact Lenses"
  By Acuity Polymers, Inc.
  510(k) number; **K240618**
  Product Code: HQD
- "Acuity 200™ (fluoroxyfocon A) Rigid Gas Permeable Contact Lens"
  By Acuity Polymers, Inc.
  510(k) number; **K201194**
  Product Code: HQD
- "Acuity 200™ (fluoroxyfocon A) Rigid Gas Permeable Contact Lens"
  By Acuity Polymers, Inc.
  510(k) number; **K203571**
  Product Code: HQD

IV. DEVICE DESCRIPTION

The SDJMASTERVISION (fluoroxyfocon A) Rigid Gas Permeable Contact Lenses are manufactured from machine latheable rigid gas permeable materials composed of siloxanyl fluoromethacrylate copolymers that are tinted for visibility and available with or without an ultraviolet (UV) light absorber.

The SDJMASTERVISION (fluoroxyfocon A) Rigid Gas Permeable Contact Lenses for daily wear are made available in spherical, toric, multifocal, scleral and aspheric designs in the following lens parameters:

Parameter	Range	Tolerance
Base Curve	4.00mm to 11.50mm	± 0.05 mm
Center Thickness	0.08mm to 0.75mm	± 0.02 mm
Diameter	7.0mm to 21.0mm	± 0.10mm
Spherical Power	-20.00D to +20.00D	± 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 9.00D	± 0.25 (0 to </= 2D) ± 0.37 (2 to </= 4D) ± 0.50 (over 4D)
Multifocal Power	+1.00D to 4.00D	± 0.25D
Surface Appearance	-	Lenses should be clear with no surface defect

The following table depicts the physical properties of the SDJMASTERVISION (fluoroxyfocon A) Rigid Gas Permeable Contact Lenses:

	Fluoroxyfocon A Rigid Gas Permeable Contact Lens
Refractive Index	1.430
Modulus (MPa)	1194
Hardness (Shore D)	78
Specific Gravity	1.18
Oxygen Permeability (Dk)	200×10^{-11} (cm^2/sec) (ml O_2/ml x mm Hg @ 35°C)
Color Additives	Visibility Tints – D&C Green #6, D&C Violet #2, Solvent Yellow 18, D&C Red #17

The SDJMASTERVISION (fluoroxyfocon A) Rigid Gas Permeable Contact Lenses are supplied dry (without storage solution) and non-sterile in a screw top case and must be cleaned and conditioned prior to use.

V. INDICATIONS FOR USE

The SDJMASTERVISION (fluoroxyfocon A) Rigid Gas Permeable Contact Lenses are 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.

The SDJMASTERVISION (fluoroxyfocon A) Rigid Gas Permeable Contact Lenses 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 lens may concurrently provide correction of refractive error.

The SDJMASTERVISION (fluoroxyfocon A) Rigid Gas Permeable Contact Lenses may be cleaned and disinfected using a chemical (not heat) lens care system.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH PREDICATE DEVICE

The SDJMASTERVISION (fluoroxyfocon A) Rigid Gas Permeable Contact Lenses are substantially equivalent to the predicate device (cleared under K240618) in terms of the following:

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

The SDJMASTERVISION (fluoroxyfocon A) Rigid Gas Permeable Contact Lenses are substantially equivalent to the predicate device (cleared under K201194) in terms of the following:

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

The SDJMASTERVISION (fluoroxyfocon A) Rigid Gas Permeable Contact Lenses are substantially equivalent to the predicate device (cleared under K203571) in terms of the following:

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

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

	SDJMASTERVISION Rigid Gas Permeable Contact Lenses	**Acuity 200™ Acuity 100™ Rigid Gas Permeable Contact Lens**	**Acuity 200™ Rigid Gas Permeable Contact Lens**	**Acuity 200™ Rigid Gas Permeable Contact Lens**
	Subject Device	**Predicate Device (K240618)**	**Predicate Device (K201194)**	**Predicate Device (K203571)**
Classification	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	Class II Lenses, Rigid Gas Permeable, Daily Wear 21 CFR 886.5916
Product Code	HQD	HQD	HQD	HQD
FDA Group #	Group # 3 Fluoro Silicone Acrylate	Group # 3 Fluoro Silicone Acrylate	Group # 3 Fluoro Silicone Acrylate	Group # 3 Fluoro Silicone Acrylate
Material (USAN)	fluoroxyfocon A	hexafocon A, fluoroxyfocon A	fluoroxyfocon A	fluoroxyfocon A
Production Method	Lathe-Cut	Lathe-Cut	Lathe-Cut	Lathe-Cut
Intended Use	Daily Wear	Daily Wear	Daily Wear	Daily Wear
Water Content (%)	<1%	<1%	<1%	<1%
UV Absorber Available	Yes	Yes	Yes	Yes

	Indications for Use
SDJMASTERVISION Rigid Gas Permeable Contact Lenses (subject device)	The SDJMASTERVISION (fluoroxyfocon A) Rigid Gas Permeable Contact Lenses are 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. The SDJMASTERVISION (fluoroxyfocon A) Rigid Gas Permeable Contact Lenses 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 lens may concurrently provide correction of refractive error. The SDJMASTERVISION (fluoroxyfocon A) Rigid Gas Permeable Contact Lenses may be cleaned and disinfected using a chemical (not heat) lens care system.
Acuity 200™ Acuity 100™ Rigid Gas Permeable Contact Lens (K240618)	The Acuity 200™ (fluoroxyfocon A), Acuity 100™ (hexafocon A), Acuity 200™ with Tangible® Hydra-PEG® (fluoroxyfocon A), and Acuity 100™ with Tangible® Hydra-PEG® Rigid Gas Permeable Contact Lenses are 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. The Acuity 200™ (fluoroxyfocon A), Acuity 100™ (hexafocon A), Acuity 200™ with Tangible® Hydra-PEG® (fluoroxyfocon A), and Acuity 100™ with Tangible® Hydra-PEG® Rigid Gas Permeable Contact Lenses 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 lens may concurrently provide correction of refractive error. The Acuity 200™ (fluoroxyfocon A), Acuity 100™ (hexafocon A), Acuity 200™ with Tangible® Hydra-PEG® (fluoroxyfocon A), and Acuity 100™ with Tangible® Hydra-PEG® Rigid Gas Permeable Contact Lenses may be cleaned and disinfected using a chemical (not heat) lens care system.
Acuity 200™ (fluoroxyfocon A) Rigid Gas Permeable Contact Lens (K201194)	The Acuity 200™ (fluoroxyfocon A) Rigid Gas Permeable Contact Lenses are 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 lens may be prescribed in spherical and aspheric powers ranging from -20.00 D to +20.00 D for daily wear.
Acuity 200™ (fluoroxyfocon A) Rigid Gas Permeable Contact Lens (K203571)	The Acuity 200™ (fluoroxyfocon A) Rigid Gas Permeable Contact Lens is 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. The Acuity 200™ (fluoroxyfocon A) Rigid Gas Permeable Contact Lens may be cleaned and disinfected using a chemical (not heat) lens care system.

VII. PERFORMANCE DATA

~ Non-Clinical Studies ~

The following testing was performed on finished SDJMASTERVISION (fluoroxyfocon A) Rigid Gas Permeable Contact Lenses:

Bench Testing—manufacturing verification testing was conducted to demonstrate the ability of Tianjin MasterVision Technology Co., Ltd. to manufacture lenses, on a repeatable basis, from fluoroxyfocon 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 fluoroxyfocon A rigid gas permeable lenses manufactured at Tianjin MasterVision 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 fluoroxyfocon A gas permeable contact lenses produced at the Tianjin MasterVision 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 the 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 the 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 the extracts from finished lenses did not induce ocular irritation.

~ Clinical Studies ~

Finished contact lenses manufactured from fluoroxyfocon A, which is a contact lens material adopted by United States Adopted Name (USAN) council, 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 SDJMASTERVISION (fluoroxyfocon 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 SDJMASTERVISION (fluoroxyfocon 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.