February 6, 2024

Metro Optics of Austin, Inc.
℅ Bret Andre
Principal Consultant
Andre Vision and Device Research
6119 Canter Lane
West Linn, OR 97068

Re: K233221
Trade/Device Name: Metro Soft, Silicone Hydrogel Daily Wear Soft Contact Lens (efrofilcon A)
Regulation Number: 21 CFR 886.5925
Regulation Name: Soft (Hydrophilic) Contact Lens
Regulatory Class: Class II
Product Code: LPL
Dated: January 10, 2024
Received: January 11, 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 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 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

Enclosure

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.

510(k) Number *(if known)*
K233221

Device Name
Metro Soft, Silicone Hydrogel Daily Wear Soft Contact Lens (efrofilcon A)

Indications for Use *(Describe)*
The Metro Soft, sphere (efrofilcon A) Silicone Hydrogel Soft Contact Lenses for daily wear are indicated for the correction of ametropia (myopia and hyperopia) in aphakic and non-aphakic persons with non-diseased eyes. The lens may be worn by persons who exhibit refractive astigmatism of 0.75 diopters or less where the astigmatism does not interfere with visual acuity.

The Metro Soft, toric (efrofilcon A) Silicone Hydrogel Soft Contact Lenses for daily wear are indicated for the correction of ametropia (myopia and hyperopia) in aphakic and non-aphakic persons with non-diseased eyes and/or possesses refractive astigmatism not exceeding 12 diopters.

The Metro Soft, multifocal (efrofilcon A) Silicone Hydrogel Soft Contact Lenses for daily wear are indicated for the correction of ametropia (myopia and hyperopia) in aphakic and non-aphakic persons with non-diseased eyes and/or possesses refractive astigmatism not exceeding 0.75 diopters and are presbyopic requiring add power of up to +4.00 diopters.

The Metro Soft, multifocal toric (efrofilcon A) Silicone Hydrogel Soft Contact Lenses for daily wear are indicated for the correction of ametropia (myopia and hyperopia) in aphakic and non-aphakic persons with non-diseased eyes and/or possesses refractive astigmatism not exceeding 4 diopters and are presbyopic requiring add power of up to +4.00 diopters.

The Metro Soft, irregular cornea (efrofilcon A) Silicone Hydrogel Soft Contact Lenses for daily wear are indicated for the correction of ametropia (myopia and hyperopia) in aphakic and non-aphakic persons and may be prescribed in otherwise non-diseased eyes that require a Soft Contact Lens for the management of irregular corneal conditions such as keratoconus and post graft fitting.

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 or hydrogen peroxide disinfection systems.

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.

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SPECIAL 510 (k) SUMMARY

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

The assigned 510(k) number is: **K233221**

I. SUBMITTER

Date Prepared:	January 5th, 2024
Name:	**Metro Optics of Austin, Inc.**
Address	15802 Vision Drive Pflugerville, TX 78660
Contact Person:	Steve Webb President
Phone number:	(512) 251-2382
Consultant/ Correspondent:	Andre Vision and Device Research Bret Andre 6119 Canter Lane West Linn, OR 97068
Phone number	(503) 372-5226

II. DEVICE

Trade Name:	**Metro Soft, Silicone Hydrogel Daily Wear Soft Contact Lens (efrofilcon A)**
Common Name:	Soft, daily wear contact lens
Classification Name:	Soft (hydrophilic) contact lens. (21 CFR 886.5925)
Regulatory Class:	Class II
Product Code:	LPL

III. PREDICATE DEVICE

The **Metro Soft, Silicone Hydrogel Daily Wear Soft Contact Lens (efrofilcon A)** is substantially equivalent to the following predicate devices:

- "**Metro Soft, Silicone Hydrogel Daily Wear Soft Contact Lens (efrofilcon A)**"
  Manufactured by Metro Optics of Austin, Inc.
  510(k) Number: K100244
- "**IntelliWave^3, Silicone Hydrogel Daily Wear Soft Contact Lens (efrofilcon A)**"
  Manufactured by Art Optical Contact Lens, Inc.
  510(k) number: K230824

IV. DEVICE DESCRIPTION

The **Metro Soft, Silicone Hydrogel Daily Wear Soft Contact Lenses** are fabricated from efrofilcon A, which in the dry (unhydrated) state may be machined and polished. The hydrophilic nature of this material allows the lens to become soft and pliable when immersed in an aqueous solution.
The non-ionic lens material, (efrofilcon A) is a daily wear silicone hydrogel contact lens that is not surface treated and characterized by a high water content. The lens material is composed of silicone monomers cross linked with other monomers and optionally incorporates RB246 (1,4-Bis[4-(2-Methacryloxyethyl) phenylamino]-9, 10-Anthraquinone)as an integrated handling tint. The lenses are made by lathe-cut for individual patients. It consists of 26% efrofilcon A and 74% water by weight when immersed in a buffered saline solution. The (efrofilcon A) name has been adopted by the United States Adopted Names Council (USAN).

In the hydrated state, the lens conforms to the curvature of the eye covering the cornea and extending slightly beyond the limbus forming a colorless, transparent optical surface. The (efrofilcon A) soft hydrophilic contact lens has a spherical back surface. The hydrophilic properties of the lens require that it be maintained in a fully hydrated state in a solution compatible with the eye. If the lens dries out, it will become hard and appear somewhat warped however, it will return to its proper configuration when completely rehydrated in the proper storage solution.

The physical properties of the **Metro Soft, Silicone Hydrogel Daily Wear Soft Contact Lens (efrofilcon A)** are as follows:

	IntelliWave^3, Silicone Hydrogel Daily Wear Soft Contact Lenses
Refractive Index (wet)	1.3770
Visible light transmission (%) @ 380-780nm	94.4%
Specific Gravity (wet)	1.049
Water Content	74±2%
Oxygen Permeability (Dk) ISO/FATT Method	56×10^{-11} (cm^2/sec) (ml O_2/ml x mm Hg @ 35°C)

The hydrophilic characteristics allow aqueous solutions to enter the lens and in its fully hydrated state the lens is approximately 74% water by weight. The lenses will be manufactured in spherical, aspherical, toric, multifocal, multifocal toric and irregular cornea configurations with the following features and properties.:

Parameter	Range	Tolerance
Base Curve	8.0mm to 9.5mm	± 0.20mm
Center Thickness	0.01mm to 0.50mm	When ≤ 0.10 mm → ±0.010 mm + 10% When > 0.10 mm → ±0.015 mm + 5%
Diameter	12.00mm to 16.00mm	± 0.20mm
Spherical Power	-20.00 D to +20.00 D (in .25D steps)	When 0.00 < |F'v| ≤ 10.00 D → ±0.25 D When 10.00 < |F'v| ≤ 20.00 D → ±0.50 D
Cylindrical Power (Toric)	-0.25 D to -12.00 D	When 0.00 < |F'v| ≤ 2.00 D → ±0.25 D When 2.00 < |F'v| ≤ 4.00 D → ±0.37 D When |F'v| > 4.00 D → ±1.00 D
Cylindrical Power (Multifocal Toric)	-0.25 D to -4.00 D	When 0.00 < |F'v| ≤ 2.00 D → ±0.25 D When 2.00 < |F'v| ≤ 4.00 D → ±0.37 D
Cylindrical Axis	1° to 180° (in 1° steps)	± 5°
Add Power (Multifocal)	+0.50 D to +4.00 D	± 0.25D

The lens is supplied sterile in vials containing a buffered saline solution. Vial labeling is printed with appropriate lot numbering, expiration dating and lens parameter identification. Expiration dating has been established based on studies of product stability, package integrity, and validation of the sterilization process.

V. INDICATIONS FOR USE

The Metro Soft, **sphere** (efrofilcon A) Silicone Hydrogel Soft Contact Lenses for daily wear are indicated for the correction of ametropia (myopia and hyperopia) in aphakic and non-aphakic persons with non-diseased eyes. The lens may be worn by persons who exhibit refractive astigmatism of 0.75 diopters or less where the astigmatism does not interfere with visual acuity.

The Metro Soft, **toric** (efrofilcon A) Silicone Hydrogel Soft Contact Lenses for daily wear are indicated for the correction of ametropia (myopia and hyperopia) in aphakic and non-aphakic persons with non-diseased eyes and/or possesses refractive astigmatism not exceeding 12 diopters.

The Metro Soft, **multifocal** (efrofilcon A) Silicone Hydrogel Soft Contact Lenses for daily wear are indicated for the correction of ametropia (myopia and hyperopia) in aphakic and non-aphakic persons with non-diseased eyes and/or possesses refractive astigmatism not exceeding 0.75 diopters and are presbyopic requiring add power of up to +4.00 diopters.

The Metro Soft, **multifocal toric** (efrofilcon A) Silicone Hydrogel Soft Contact Lenses for daily wear are indicated for the correction of ametropia (myopia and hyperopia) in aphakic and non-aphakic persons with non-diseased eyes and/or possesses refractive astigmatism not exceeding 4 diopters and are presbyopic requiring add power of up to +4.00 diopters.

The Metro Soft, **irregular cornea** (efrofilcon A) Silicone Hydrogel Soft Contact Lenses for daily wear are indicated for the correction of ametropia (myopia and hyperopia) in aphakic and non-aphakic persons and may be prescribed in otherwise non-diseased eyes that require a Soft Contact Lens for the management of irregular corneal conditions such as keratoconus and post graft fitting.

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 or hydrogen peroxide disinfection systems.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH PREDICATE DEVICE

The **Metro Soft, Silicone Hydrogel Daily Wear Soft Contact Lens (efrofilcon A)** is substantially equivalent to the Metro Soft, Silicone Hydrogel Daily Wear Soft Contact Lens (efrofilcon A) (predicate device - K100244) in the following areas:

- USAN Material (efrofilcon A)
- Manufacturing facility, procedures and controls
- Product code (LPL)
- Classification (Class II) – Soft (hydrophilic) contact lens. (21 CFR 886.5925)
- FDA material group – group V silicone hydrogel
- Lathe cut manufacturing process
- Lens designs (spherical, aspherical, toric, multifocal, multifocal toric and irregular cornea)
- Actions and intended use

The following table depicts the classification and technical characteristics of the **Metro Soft, Silicone Hydrogel Daily Wear Soft Contact Lens (efrofilcon A)** in comparison with the predicate devices.

	Metro Soft, Silicone Hydrogel Daily Wear Soft Contact Lens	**Metro Soft, Silicone Hydrogel Daily Wear Soft Contact Lens**	**IntelliWave^3 Silicone Hydrogel Daily Wear Soft Contact Lenses**
	Subject Device	***Predicate Device***	***Predicate Device***
510(k) Number		K100244	K230824
Intended Use	Daily Wear	Daily Wear	Daily Wear
Device and Classification	Class II Soft (hydrophilic) contact lens. (21 CFR 886.5925)	Class II Soft (hydrophilic) contact lens. (21 CFR 886.5925)	Class II Soft (hydrophilic) contact lens. (21 CFR 886.5925)
Product Code	LPL	LPL	LPL
Production Method	Lathe-cut	Lathe-cut	Lathe-cut
Material (USAN)	Efrofilcon A	Efrofilcon A	Efrofilcon A
FDA Group #	Group # V Silicone Hydrogel	Group # V Silicone Hydrogel	Group # V Silicone Hydrogel
Refractive Index (wet)	1.3770	1.3762	1.3770
Visible light transmission (%) @ 380-780nm	94.4%	97.4%	94.4%
Specific Gravity (wet)	1.049	1.048	1.049
Water Content	74±2%	74±2%	74±2%
Oxygen Permeability (Dk) ISO/FATT Method	56.0×10^{-11} (cm^2/sec) (ml O_2/ml x mm Hg @ 35°C)	59.8×10^{-11} (cm^2/sec) (ml O_2/ml x mm Hg @ 35°C)	56.0×10^{-11} (cm^2/sec) (ml O_2/ml x mm Hg @ 35°C)
Refractive Index (wet)	1.3770	1.3762	1.3770

	Indications for Use
Metro Soft, Silicone Hydrogel Daily Wear Soft Contact Lens (efrofilcon A) (Subject Device)	The Metro Soft, sphere (efrofilcon A) Silicone Hydrogel Soft Contact Lenses for daily wear are indicated for the correction of ametropia (myopia and hyperopia) in aphakic and non-aphakic persons with non-diseased eyes. The lens may be worn by persons who exhibit refractive astigmatism of 0.75 diopters or less where the astigmatism does not interfere with visual acuity. The Metro Soft, toric (efrofilcon A) Silicone Hydrogel Soft Contact Lenses for daily wear are indicated for the correction of ametropia (myopia and hyperopia) in aphakic and non-aphakic persons with non-diseased eyes and/or possesses refractive astigmatism not exceeding 12 diopters. The Metro Soft, multifocal (efrofilcon A) Silicone Hydrogel Soft Contact Lenses for daily wear are indicated for the correction of ametropia (myopia and hyperopia) in aphakic and non-aphakic persons with non-diseased eyes and/or possesses refractive astigmatism not exceeding 0.75 diopters and are presbyopic requiring add power of up to +4.00 diopters. The Metro Soft, multifocal toric (efrofilcon A) Silicone Hydrogel Soft Contact Lenses for daily wear are indicated for the correction of ametropia (myopia and hyperopia) in aphakic and non-aphakic persons with non-diseased eyes and/or possesses refractive astigmatism not exceeding 4 diopters and are presbyopic requiring add power of up to +4.00 diopters. The Metro Soft, irregular cornea (efrofilcon A) Silicone Hydrogel Soft Contact Lenses for daily wear are indicated for the correction of ametropia (myopia and hyperopia) in aphakic and non-aphakic persons and may be prescribed in otherwise non-diseased eyes that require a Soft Contact Lens for the management of irregular corneal conditions such as keratoconus and post graft fitting. 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 or hydrogen peroxide disinfection systems.
Metro Soft, Silicone Hydrogel Daily Wear Soft Contact Lens (efrofilcon A) (Predicate Device: K100244)	The Metro Soft, sphere (efrofilcon A) Silicone Hydrogel Soft Contact Lenses for daily wear are indicated for the correction of ametropia (myopia and hyperopia) in aphakic and non-aphakic persons with non-diseased eyes. The lens may be worn by persons who exhibit refractive astigmatism of 0.75 diopters or less where the astigmatism does not interfere with visual acuity. The Metro Soft, toric (efrofilcon A) Silicone Hydrogel Soft Contact Lenses for daily wear are indicated for the correction of ametropia (myopia and hyperopia) in aphakic and non-aphakic persons with non-diseased eyes and/or possesses refractive astigmatism not exceeding 12 diopters. The Metro Soft, multifocal (efrofilcon A) Silicone Hydrogel Soft Contact Lenses for daily wear are indicated for the correction of ametropia (myopia and hyperopia) in aphakic and non-aphakic persons with non-diseased eyes and/or possesses refractive astigmatism not exceeding 0.75 diopters and are presbyopic requiring add power of up to +4.00 diopters. The Metro Soft, multifocal toric (efrofilcon A) Silicone Hydrogel Soft Contact Lenses for daily wear are indicated for the correction of ametropia (myopia and hyperopia) in aphakic and non-aphakic persons with non-diseased eyes and/or possesses refractive astigmatism not exceeding 4 diopters and are presbyopic requiring add power of up to +4.00 diopters. The Metro Soft, irregular cornea (efrofilcon A) Silicone Hydrogel Soft Contact Lenses for daily wear are indicated for the correction of ametropia (myopia and hyperopia) in aphakic and non-aphakic persons and may be prescribed in otherwise non-diseased eyes that require a Soft Contact Lens for the management of irregular corneal conditions such as keratoconus and post graft fitting. 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 or hydrogen peroxide disinfection systems.

IntelliWave³ Silicone Hydrogel Daily Wear Soft Contact Lenses (Predicate Device: K230824)	The **IntelliWave3 sphere** (efrofilcon A) Silicone Hydrogel Soft Contact Lenses for daily wear are indicated for the correction of ametropia (myopia and hyperopia) in aphakic and non-aphakic persons with non-diseased eyes. The lens may be worn by persons who exhibit refractive astigmatism of .75 diopters or less where the astigmatism does not interfere with visual acuity. The **IntelliWave3 toric** (efrofilcon A) Silicone Hydrogel Soft Contact Lenses for daily wear are indicated for the correction of ametropia (myopia and hyperopia) in aphakic and non-aphakic persons with non-diseased eyes and/or possesses refractive astigmatism not exceeding 12 diopters. The **IntelliWave3 multifocal** (efrofilcon A) Silicone Hydrogel Soft Contact Lenses for daily wear are indicated for the correction of ametropia (myopia and hyperopia) in aphakic and non-aphakic persons with non-diseased eyes and/or possesses refractive astigmatism not exceeding .75 diopters and are presbyopic requiring add power of up to +4.00 diopters. The **IntelliWave3 multifocal-toric** (efrofilcon A) Silicone Hydrogel Soft Contact Lenses for daily wear are indicated for the correction of ametropia (myopia and hyperopia) in aphakic and non-aphakic persons with non-diseased eyes and/or possesses refractive astigmatism not exceeding 4 diopters and are presbyopic requiring add power of up to +4.00 diopters. The **IntelliWave3 irregular cornea** (efrofilcon A) Silicone Hydrogel Soft Contact Lenses for daily wear are indicated for the correction of ametropia (myopia and hyperopia) in aphakic and non-aphakic persons and may be prescribed in otherwise non-diseased eyes that require a Soft Contact Lens for the management of irregular corneal conditions such as keratoconus and post graft fitting. 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 or hydrogen peroxide disinfection systems.

VII. PERFORMANCE DATA

~ Non-Clinical Studies ~

The following non-clinical testing was performed on **Metro Soft, Silicone Hydrogel Daily Wear Soft Contact Lens (efrofilcon A)**:

Bench Testing—manufacturing verification testing was conducted to demonstrate our firm's ability to manufacture the finished lenses, on a repeatable basis, from supplied lens blanks to a variety of prescribed parameters. All lenses were manufactured to established finished product specifications within the ANSI Z80.20 tolerance.

Shelf Life—Testing was performed to evaluate the stability, sterility, and package integrity of the lenses over the duration of the labeled expiration date. The data presented supports establishment of the proposed shelf life.

Toxicology—All biocompatibility/toxicology tests were conducted in accordance with the GLP regulation.

- 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 are considered not acutely systemically toxic.

- Acute Ocular Irritation: Acute ocular irritation testing was performed in accordance with ISO 10993-10, and the extracts from finished lenses produced no ocular irritation.

The following non-clinical testing was performed previously or by the lens material manufacturer for finished contact lenses manufactured from efroficon A contact lens blanks:

Toxicology—All biocompatibility/toxicology tests were conducted in accordance with the GLP regulation.

- Skin Sensitization Study (Maximization Test): The skin sensitization study was conducted on the finished lenses in accordance with ISO 10993-10, and the contact lens extracts did not produce skin sensitization.
- 22-Day Ocular Irritation: The 22-day ocular irritation test was conducted in accordance with ISO 9394 on the finished lenses, and the finished contact lenses produced no ocular irritation.

The biocompatibility of the primary packaging and packaging solution have been previously addressed under the predicate K100244 and there are no changes to these components as compared to the predicate.

Performance Testing—The following bench tests were completed: refractive index, water content, Dk, % transmission, tensile strength, modulus, % elongation to break, specific gravity and quantification of polymerization residuals. Results of physicochemical and mechanical property testing demonstrate consistent material properties between the efrofilcon A, Silicone Hydrogel Daily Wear Soft Contact Lenses and the predicate device.

Preservative Uptake and Release—efrofilcon A, Silicone Hydrogel Daily Wear Soft Contact Lenses were analyzed for uptake and release of preservatives found in lens care products. Testing was conducted according to ISO 11986:2017, Ophthalmic optics - Contact lenses and contact lens care products - Determination of preservative uptake and release. Uptake and release profiles of efrofilcon A contact lenses for the preservatives tested demonstrate sub-detection limit amounts of release at each time point evaluated.

Solution Compatibility—The physical compatibility of efrofilcon A, Silicone Hydrogel Daily Wear Soft Contact Lenses with commonly available cleaning and disinfection solutions (peroxide and MPDS) was confirmed following the methodology described in ISO 11981:2017, Ophthalmic optics - Contact lenses and contact lens care products - Determination of physical compatibility of contact lens care products with contact lenses.

~ Clinical Studies ~

Clinical testing was not necessary for this application.

~ Conclusions Drawn from Testing ~

Results from testing presented in this premarket notification for the **Metro Soft, Silicone Hydrogel Daily Wear Soft Contact Lens (efrofilcon A)** demonstrate no relevant differences from the predicate devices and support the substantial equivalence claim.

VIII. CONCLUSIONS

Substantial Equivalence

Information presented in this premarket notification establishes that **Metro Soft, Silicone Hydrogel Daily Wear Soft Contact Lens (efrofilcon A)** for daily wear are as safe and effective as the predicate device when used in accordance with the labeled directions for use and for the proposed indications.

Risks and Benefits

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