



September 6, 2023

Art Optical Contact Lens, Inc.
% Bret Andre
Principal Consultant
EyeReg Consulting Inc.
6119 Canter Lane
West Linn, Oregon 97068

Re: K230824

Trade/Device Name: IntelliWave3, 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: August 1, 2023
Received: August 2, 2023

Dear Mr. 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 (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 located 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.

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 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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,


Elvin Y. Ng -S

for 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

510(k) Number (if known)
K230824

Device Name
IntelliWave3, Silicone Hydrogel Daily Wear Soft Contact Lens (efofilcon A)

Indications for Use (Describe)

The IntelliWave3 sphere (efofilcon 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 (efofilcon 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 (efofilcon 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 (efofilcon 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 (efofilcon 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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510 (k) SUMMARY

This 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: K230824

I. SUBMITTER

Date Prepared: August 31st, 2023

Name: **Art Optical Contact Lens, Inc.**
Address 3175 3 Mile Rd NW
 Grand Rapids, MI 49534

Contact Person: Jill Anastor
 President

Phone number: (630) 530-9700

Consultant/
Correspondent: EyeReg Consulting, Inc.
 Bret Andre
 6119 Canter Lane
 West Linn, OR 97068

Phone number (503) 372-5226

II. DEVICE

Trade Name: **IntelliWave³, 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 **IntelliWave³ Silicone Hydrogel Daily Wear Soft Contact Lenses** are substantially equivalent to the following predicate device:

- “**IntelliWave³, Silicone Hydrogel Daily Wear Soft Contact Lens (efofilcon A)**”
Manufactured by Art Optical Contact Lens, Inc.
510(k) number; K100221

IV. DEVICE DESCRIPTION

The **IntelliWave³ Silicone Hydrogel Daily Wear Soft Contact Lenses** are fabricated from efofilcon 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, (efofilcon A) is a group 2, 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. The lenses are made by lathe-cut for custom RX. It consists of 26% efofilcon A and 74% water by weight when immersed in a buffered saline solution. The (efofilcon 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 (efofilcon 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 **IntelliWave³ Silicone Hydrogel Daily Wear Soft Contact Lenses** are as follows:

	IntelliWave³, 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	7.4mm to 9.5mm	± 0.20mm
Center Thickness	0.01mm to 0.60mm	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	-23.50 D to +23.50 D (in .25D steps)	When $0.00 < F'v \leq 10.00$ D → ±0.25 D When $10.00 < F'v \leq 20.00$ D → ±0.50 D
Cylindrical Power (Toric)	-0.25 D to -12.00 D	When $0.00 < F'v \leq 2.00$ D → ±0.25 D When $2.00 < F'v \leq 4.00$ 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 $0.00 < F'v \leq 2.00$ D → ±0.25 D When $2.00 < F'v \leq 4.00$ D → ±0.37 D When $ F'v > 4.00$ D → ±1.00 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 **IntelliWave³ sphere** (efofilcon 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** (efofilcon 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** (efofilcon 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** (efofilcon 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** (efofilcon 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

IntelliWave³ Silicone Hydrogel Daily Wear Soft Contact Lenses are substantially equivalent to the IntelliWave³, Silicone Hydrogel Daily Wear Soft Contact Lens (efrofilcon A) (predicate device - K100221) 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 **IntelliWave³ Silicone Hydrogel Daily Wear Soft Contact Lenses** in comparison with the predicate devices.

	IntelliWave ³ , Silicone Hydrogel Daily Wear Soft Contact Lenses	IntelliWave ³ Silicone Hydrogel Daily Wear Soft Contact Lenses
	<i>Subject Device</i>	<i>Predicate Device</i>
510(k) Number		K100221
Intended Use	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)
Product Code	LPL	LPL
Production Method	Lathe-cut	Lathe-cut
Material (USAN)	Efrofilcon A	Efrofilcon A
FDA Group #	Group # V Silicone Hydrogel	Group # V Silicone Hydrogel
Refractive Index (wet)	1.3770	1.3762
Visible light transmission (%) @ 380-780nm	94.4%	97.4%
Specific Gravity (wet)	1.049	1.048
Water Content	74±2%	74±2%
Oxygen Permeability (Dk) ISO/FATT Method	56.0 x 10 ⁻¹¹ (cm ² /sec) (ml O ₂ /ml x mm Hg @ 35°C)	59.8 x 10 ⁻¹¹ (cm ² /sec) (ml O ₂ /ml x mm Hg @ 35°C)
Refractive Index (wet)	1.3770	1.3762

	Indications for Use
<p>IntelliWave³, Silicone Hydrogel Daily Wear Soft Contact Lenses (Subject Device)</p>	<p>The IntelliWave³ sphere (efofilcon 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.</p> <p>The IntelliWave³ toric (efofilcon 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.</p> <p>The IntelliWave³ multifocal (efofilcon 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.</p> <p>The IntelliWave³ multifocal-toric (efofilcon 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.</p> <p>The IntelliWave³ irregular cornea (efofilcon 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.</p> <p>Eye care 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.</p>
<p>IntelliWave³ Silicone Hydrogel Daily Wear Soft Contact Lenses (Predicate Device: K100221)</p>	<p>The IntelliWave³ sphere (efofilcon 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.</p> <p>The IntelliWave³ toric (efofilcon 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.</p> <p>The IntelliWave³ multifocal (efofilcon 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.</p> <p>The IntelliWave³ multifocal-toric (efofilcon 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.</p> <p>The IntelliWave³ irregular cornea (efofilcon 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.</p> <p>Eye care 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.</p>

VII. PERFORMANCE DATA

~ Non-Clinical Studies ~

Following non-clinical testing was performed on **IntelliWave³ Silicone Hydrogel Daily Wear Soft Contact Lenses**:

Bench Testing—manufacturing verification testing was conducted to demonstrate the ability of Art Optical Contact Lens, Inc. to manufacture IntelliWave³, Silicone Hydrogel Daily Wear Soft Contact 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.

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 efofilcon A, Silicone Hydrogel Daily Wear Soft Contact Lenses and the predicate device.

Shelf Life—Testing was performed to evaluate the stability, sterility, and package integrity of the IntelliWave³, Silicone Hydrogel Daily Wear Soft Contact 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.
- **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.

Biocompatibility of the primary packaging and packaging solution has been previously addressed under the predicate K100221 and there are no changes to these components as compared to the predicate.

Preservative Uptake and Release—efofilcon 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 efofilcon 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 efofilcon 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 **IntelliWave³, Silicone Hydrogel Daily Wear Soft Contact Lenses** demonstrate no relevant differences from the predicate devices and supports the substantial equivalence claim.

VIII. CONCLUSIONS

Substantial Equivalence

Information presented in this premarket notification establishes that **IntelliWave³, Silicone Hydrogel Daily Wear Soft Contact Lenses** 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.