September 6, 2019

Lentechs, LLC
℅ Mr. Bret Andre
Principal Consultant
EyeReg Consulting, Inc.
6119 Canter Lane
West Linn, OR 97068

Re: K191121
Trade/Device Name: Apioc (efrofilcon A) Soft (hydrophilic) Silicone Hydrogel Contact Lens, Apioc P for Presbyopia (efrofilcon A) Soft (hydrophilic) Silicone Hydrogel Contact Lens, Apioc A for Astigmatism (efrofilcon A) Soft (hydrophilic) Silicone Hydrogel Contact Lens, Apioc AP (efrofilcon A) Soft (hydrophilic) Silicone Hydrogel Contact Lens
Regulation Number: 21 CFR 886.5925
Regulation Name: Soft (Hydrophilic) Contact Lens
Regulatory Class: Class II
Product Code: LPL
Dated: July 9, 2019
Received: July 10, 2019

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,

for 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K191121

Device Name
Apioc (efrofilcon A) Soft (hydrophilic) Silicone Hydrogel Contact Lens; Apioc P for Presbyopia (efrofilcon A) Soft (hydrophilic) Silicone Hydrogel Contact Lens; Apioc A for Astigmatism (efrofilcon A) Soft (hydrophilic) Silicone Hydrogel Contact Lens; Apioc AP (efrofilcon A) Soft (hydrophilic) Silicone Hydrogel Contact Lens

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

The Apioc P, multifocal (efrofilcon A) Silicone Hydrogel Soft Contact Lenses for daily wear are indicated for the correction of refractive ametropia (myopia and hyperopia) and presbyopia 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 Apioc AP, multifocal toric (efrofilcon A) Silicone Hydrogel Soft Contact Lenses for daily wear are indicated for the correction of ametropia (myopia and hyperopia) and presbyopia in aphakic and non-aphakic persons with non-diseased eyes and/or possesses refractive astigmatism not exceeding 12 diopters and are presbyopic requiring add power of up to +4.00 diopters.

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.

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

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510 (k) SUMMARY OF SAFETY AND EFFECTIVENESS

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

The assigned 510(k) number is: **K191121**

I. SUBMITTER

Date Prepared: August 28th, 2019

Name: **Lentechs, LLC**
Address: 1275 Kinnear Road,
Columbus, Ohio 43212
United States

Contact Person: Mr. Robin Sears
President and CEO
Phone number: (614) 487-3700

Consultant: Bret Andre
EyeReg Consulting, Inc.
6119 Canter Ln.
West Linn, OR 97068
Phone number: (503) 372-5226

II. DEVICE

Trade Name: **Apioc (efrofilcon A) Soft (hydrophilic) Silicone Hydrogel Contact Lens**
Apioc P for Presbyopia (efrofilcon A) Soft (hydrophilic) Silicone Hydrogel Contact Lens
Apioc A for Astigmatism (efrofilcon A) Soft (hydrophilic) Silicone Hydrogel Contact Lens
Apioc AP (efrofilcon A) Soft (hydrophilic) Silicone Hydrogel Contact Lens

Common Name: Contact Lens, Daily Wear

Classification Name: Soft (hydrophilic) Contact Lens (21 CFR 886.5925)

Regulatory Class: Class II

Product Code: LPL

III. PREDICATE DEVICE

The **Apioc, Apioc P, Apioc A, and Apioc AP (efrofilcon A) Soft (hydrophilic) Silicone Hydrogel Contact Lenses** are substantially equivalent to the following predicate device:

- "IntelliWave 3, Silicone Hydrogel Daily Wear Soft Contact Lens (efrofilcon A)"
  Art Optical Contact Lens, Inc.
  510(k) number; **K100221**
  Primary Predicate

IV. DEVICE DESCRIPTION

The **Apioc , Apioc P, Apioc A, and Apioc AP (efrofilcon A) Soft (hydrophilic) Silicone Hydrogel Contact Lenses** are designed with a lenticular zone for attachment to the upper eyelid. The 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 composed of silicone monomers cross linked with other monomers and optionally incorporates D&C Green 6 as an integrated handling tint. The material 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 **Apioc, Apioc P, Apioc A, and Apioc AP** Contact Lens with UV Blocker and center thickness of 0.18mm, a Benzophenone UV absorbing monomer is used to block UV radiation. The UV blocking for lenses averages > 98% in the UVB range of 280nm – 315nm and >70% in the UVA range of 316 – 380nm.

The **Apioc, Apioc P, Apioc A, and Apioc AP (efrofilcon A) Soft (hydrophilic) Silicone Hydrogel Contact Lenses** will be manufactured in the sphere, aspheric, toric, multifocal, and multifocal toric design configurations. The material properties and available parameters of the finished lenses are as follows:

Parameter	Range	Tolerance*
Chord Diameter	9.00 mm to 16.00 mm	±0.25 mm
Center Thickness	0.01 mm to 0.50 mm	When ≤ 0.10 mm → ±0.010 mm + 10% When > 0.10 mm → ±0.015 mm + 5%
Base Curve	7.00 mm to 10.0 mm	±0.25 mm
Back Vertex Power (F'v)	+20.00D to -20.00D (in 0.25D steps)	When 0.00 < |F'v| ≤ 10.00 D → ±0.25 D When 10.00 < |F'v| ≤ 20.00 D → ±0.50 D
Cylinder Power (F'c)	-0.25D to -10.00D (in 0.25D steps)	When 0.00 < |F'c| ≤ 2.00 D → ±0.25 D When 2.00 < |F'c| ≤ 4.00 D → ±0.37 D |F'c| ≤ 4.00 D → ±0.50 D
Cylinder Axis	10° to 180° (in 10° steps)	When 0.00 < |F'c| ≤ 1.50 D → ± 8° When|F'c| > 1.50 D → ± 5°

Multifocal Add	Up to +4.00 D (in 0.50D steps)	±0.37 D
Surface Appearance	-	Lenses should be clear with no surface defect
Oxygen Permeability (x 10^{-11}(cm^2/sec)(mlO2)/(ml x hPa))	59.8	±20%
Light Transmission - Tinted (@ 380-780nm)	>97%	±5%
Ultraviolet Radiation Transmittance	<2% T_{UVB} <30% T_{UVA}	$T_{UVB\ (280\ to\ 315\ nm)} < 0.05T_V$ $T_{UVA\ (316\ to\ 380\ nm)} < 0.50T_V$
Water Content	74%	±2%
Refractive Index	1.380 (hydrated)	±0.005

*ANSI Z80.20, Ophthalmics – Contact Lenses – Standard Terminology, Tolerances, Measurements And Physicochemical Properties (2016)

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

The **Apioc P,** multifocal (efrofilcon A) Silicone Hydrogel Soft Contact Lenses for daily wear are indicated for the correction of refractive ametropia (myopia and hyperopia) and presbyopia 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 **Apioc AP,** multifocal toric (efrofilcon A) Silicone Hydrogel Soft Contact Lenses for daily wear are indicated for the correction of ametropia (myopia and hyperopia) and presbyopia in aphakic and non-aphakic persons with non-diseased eyes and/or possesses refractive astigmatism not exceeding 12 diopters and are presbyopic requiring add power of up to +4.00 diopters.

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 **Apioc , Apioc P, Apioc A, and Apioc AP (efrofilcon A) Soft (hydrophilic) Silicone Hydrogel Contact Lenses** are substantially equivalent to IntelliWave 3, Silicone Hydrogel Daily Wear Soft Contact Lens (efrofilcon A) (cleared under K100221) in terms of the following:

- FDA classification (21 CFR 886.5925)
- FDA group 2 (>50% H2O, non-ionic polymer)
- USAN contact lens material (efrofilcon A)
- Intended use – daily wear contact lenses
- Indications for use
- Actions
- Lathe cut production method

The **Apioc , Apioc P, Apioc A, and Apioc AP (efrofilcon A) Soft (hydrophilic) Silicone Hydrogel Contact Lenses** are designed with aspheric optics and a lenticular zone for attachment to the upper eyelid, which differs from the predicate device design (cleared under K100221). These differences in the dimensional parameters of the lens are non-significant and will not affect the safety and effectiveness of the new device.

The following matrix illustrates the production method, lens function and material characteristics of the **Apioc , Apioc P, Apioc A, and Apioc AP (efrofilcon A) Soft (hydrophilic) Silicone Hydrogel Contact Lenses**, as well as the predicate device.

Substantial Equivalence Matrix

	Lentechs, LLC **Apioc , Apioc P, Apioc A, and Apioc AP (efrofilcon A) Soft (hydrophilic) Silicone Hydrogel Contact Lenses (Subject Device)**	**Art Optical Contact Lens, Inc.** **IntelliWave 3, Silicone Hydrogel Daily Wear Soft Contact Lens (efrofilcon A) (Predicate)** **510(k) K100221**
Indications for Use	The Apioc, sphere/aspheric (efrofilcon A) Silicone Hydrogel Soft Contact Lenses for daily wear are indicated for the correction of refractive 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 Apioc A, toric (efrofilcon A) Silicone Hydrogel Soft Contact Lenses for daily wear are indicated for the correction of refractive ametropia (myopia and hyperopia) in aphakic and non-aphakic persons with non-diseased eyes and/or possesses refractive astigmatism not exceeding 12 diopters. The Apioc P, multifocal (efrofilcon A) Silicone Hydrogel Soft Contact Lenses for daily wear are indicated for the correction of refractive ametropia (myopia and hyperopia) and presbyopia 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 IntelliWave 3, 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 IntelliWave 3, 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 IntelliWave 3, multifocal (efrofileon 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)

	The Apioc AP, multifocal toric (efrofilcon A) Silicone Hydrogel Soft Contact Lenses for daily wear are indicated for the correction of ametropia (myopia and hyperopia) and presbyopia in aphakic and non-aphakic persons with non-diseased eyes and/or possesses refractive astigmatism not exceeding 12 diopters and are presbyopic requiring add power of up to +4.00 diopters. 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.	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 nan-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.
Functionality	The contact lenses act as a refractive medium that focus light rays from near and distant objects on the retina	The contact lenses act as a refractive medium that focus light rays from near and distant objects on the retina
FDA Classification	Soft (hydrophilic) Contact Lens (21 CFR 886.5925)	Soft (hydrophilic) Contact Lens (21 CFR 886.5925)
FDA Group	FDA Group 2 (>50% H_2O, non-ionic polymer)	FDA Group 2 (>50% H_2O, non-ionic polymer)
Production Method	Lathe Cut	Lathe Cut
USAN name	Efrofilcon A	Efrofilcon A
Water Content (%)	74±2%	74±2%
Oxygen Permeability x 10^{-11} (cm^2/sec)(mlO_2)/(ml x hPa @ 35°C))	59.8	59.8
Refractive Index (hydrated)	1.380	1.380
UV Blocker	Yes	Yes

VII. PERFORMANCE DATA

The following performance data were provided in support of the substantial equivalence determination.

Non-clinical Testing

Non-clinical testing for finished contact lenses manufactured from efrofilcon A blanks has been demonstrated previously. Additional non-clinical testing was conducted to support the claim that the Apioc, Apioc P, Apioc A, and Apioc AP (efrofilcon A) Soft (hydrophilic) Silicone Hydrogel Contact Lenses are substantially equivalent to the currently marketed predicate devices. A summary of the results from the non-clinical studies is presented below.

Stability:

Testing was performed to demonstrate the stability of the parameters and features of the Apioc, Apioc P, Apioc A, and Apioc AP (efrofilcon A) finished contact lenses over the proposed shelf life. The data presented supports substantial equivalence of the Apioc , Apioc P, Apioc A, and Apioc AP (efrofilcon A) finished contact lenses to the predicate device.

Lens Design/Manufacturing Verification:

Bench testing was performed to verify the ability of Lentechs, Inc. to manufacture the Apioc P, Apioc A, and Apioc AP (efrofilcon A) finished contact lenses to a variety of prescribed parameters within manufacturing tolerances.

Clinical Testing

Clinical testing is not required. The clinical performance of soft (hydrophilic) contact lenses manufactured from efrofilcon A materials has been demonstrated previously.

VIII. CONCLUSIONS

Validity of Scientific Data

Laboratories under Good Laboratory Practice regulations conducted toxicology, microbiology, and shelf-life stability 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 **Apioc , Apioc P, Apioc A, and Apioc AP (efrofilcon A) Soft (hydrophilic) Silicone Hydrogel Contact Lenses** are as safe and effective as the predicate device when used in accordance with the labeled directions for use and for the proposed indication.

Risks and Benefits

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