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: **K133403**

Applicant information:

Date Prepared:	June 6, 2014
Name:	Firestone Optics
Address	3901 NE 33rd Terrace Kansas City, MO 64117
Contact Person:	David T Rusch President
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Phone number	(970) 243 5490
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Device Information:

Device Class:	2
Regulation Number:	886.5925
Product Code:	LPL
Regulation Description:	Soft (hydrophilic) contact lens.

Device Trade Name:

FireSoft-SiHy (efrofilcon A) Silicone Hydrogel (Spherical, Toric, Multifocal, Multifocal Toric)

FireSoft-IC (efrofilcon A) Silicone Hydrogel (Irregular Cornea; Keratoconus, Post Graft)

FireSoft-55 (methafilcon A) Hydrogel (Spherical, Toric, Multifocal, Multifocal Toric,)

FireSoft-49G (hioxifilcon B) Hydrogel (Spherical, Toric, Multifocal, Multifocal Toric)

FireSoft-54G (hioxifilcon D) Hydrogel (Spherical, Toric, Multifocal, Multifocal Toric)

Equivalent Devices:

The **FireSoft** Daily Wear Soft Contact Lenses are substantially equivalent to the following predicate devices:

Predicate devices:

"Soft K Keratoconus" (efrofilcon A)
by Soflex Limited
510(k) number; **K122220**

"IntelliWave3" (efrofilcon A)
by Art Optical Contact Lens, Inc.
510(k) number; **K100221**

"Contaflex 55" (methafilcon A)
by Contamac Ltd.
510(k) number; **K023989**

"Alden HP 54" (hioxifilcon D)
by Alden Optical Labs, Inc.
510(k) number: **K091327**

"Alden HP 49" (hioxifilcon B)
by Alden Optical Labs, Inc.
510(k) number: **K981252**

Device Description:

The **FireSoft-SiHy** (efrofilcon A) and **FireSoft-IC** (efrofilcon A) Silicone Hydrogel 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 group 5, 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 D&C Green 6 as an integrated handling tint. The lenses are made by lathe-cut for individualized RX. 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).

The unique base curve geometry of the **FireSoft-IC** lens has a spheric optic zone with an aspheric periphery. The front curve has a reinforced optic zone with a center thickness of.36mm (standard), with a special lenticular zone for structural stability. The design incorporates pressure balancing holes to equalize the pressure between the front and back of the lens to improve; Optic stability, Oxygen transmissibility, Tear exchange, and Eliminate air bubbles.

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 lens are:

Refractive Index	1.38
Light Transmission	greater than 97%
Surface Character	hydrophilic
Water Content	74 %
Specific Gravity	1.048 (hydrated)
Oxygen Permeability	59.8×10^{-11} (cm^2/sec) (ml O_2/ml x hPa @ 35°C), (revised Fatt method).

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 and irregular cornea configurations with the following features and properties.

- Chord Diameter 12.0 mm to 16.00 mm
- Center Thickness 0.01 mm to 0.50 mm
- Base Curve 8.0 mm to 9.5 mm
- Power Range -20.00D to +20.00D in 0.25 steps
- Cylinder Power (Toric) -0.25D to -10.00D
- Add Power* (Multifocal) +0.50D to +3.00D

* not applicable for the FireSoft-IC

The **FireSoft-55** (methafilcon A) Hydrogel Soft Contact Lenses are fabricated from methafilcon 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 ionic lens material, (methafilcon A) is a co-polymer of 2-Hydroxyethylmethacrylate (2-HEMA) and Methacrylic Acid, cross-linked with ethylene glycol dimethacrylate (EGDMA), plus an initiator. The co-polymer consists of 45% methafilcon A and 55% water by weight when immersed in normal buffered saline solution. The lens is available in clear and with a blue visibility-handling tint, [phthalocyaninato (2-)] copper. The methafilcon 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 (methafilcon 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 hydrophilic characteristics allow aqueous solutions to enter the lens and in its fully hydrated state the lens is approximately 55% water by weight. The physical properties of the lens are:

Refractive Index	1.405 (hydrated)
Light Transmission (clear)	greater than 94%
Light Transmission (tinted)	greater than 94%
Water Content	55 % ± 2%
Specific Gravity	1.067
Oxygen Permeability	19.6×10^{-11} (cm^2/sec) (ml O_2/ml x mm Hg @ 35°C), (revised Fatt method).

The **FireSoft-55** lenses will be manufactured in spherical, toric and multifocal configurations with the following features.

• Chord Diameter	12.0 mm to 16.00 mm
• Center Thickness	0.01 mm to 0.50 mm
• Base Curve	8.0 mm to 9.5 mm
• Power Range	-20.00D to +20.00D in 0.25 steps
• Cylinder Power (Toric)	-0.25D to -10.00D
• Add Power (Multifocal)	+0.50D to +3.00D

The **FireSoft-49G (hioxifilcon B)** Hydrogel Soft Contact Lenses are fabricated from (hioxifilcon B) which is a non-ionic, ultra high molecular weight copolymer of 2-hydroxyethyl methacrylate (2-HEMA) and 2,3-Dihydroxypropyl Methacrylate (Glycerol Methacrylate, GMA). It consists of 51% hioxifilcon B and 49% water by weight when immersed in normal buffered saline solution. The lens is available in clear and with a blue visibility handling tint, phthalocyanato (2) - (copper). The hioxifilcon B 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 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 hydrophilic characteristics allow aqueous solutions to enter the lens and in its fully hydrated state the lens is approximately 49% water by weight. The physical properties of the lens are:

Refractive Index	1.425 (hydrated)
Light Transmission (clear)	greater than 95%
Light Transmission (tinted)	greater than 95%
Water Content	49 % ± 2%
Specific Gravity	1.137
Oxygen Permeability	15.0×10^{-11} (cm^2/sec) (ml O_2/ml x mm Hg @ 35°C), (revised Fatt method).

The **FireSoft-49G** lenses will be manufactured in spherical, toric and multifocal configurations with the following features.

• Chord Diameter	12.0 mm to 16.00 mm
• Center Thickness	0.01 mm to 0.50 mm
• Base Curve	8.0 mm to 9.5 mm
• Power Range	-20.00D to +20.00D in 0.25 steps
• Cylinder Power (Toric)	-0.25D to -10.00D
• Add Power (Multifocal)	+0.50D to +3.00D

The **FireSoft-54G (hioxifilcon D)** Hydrogel Soft Contact Lenses are fabricated from (hioxifilcon D) which is a non-ionic, ultra high molecular weight copolymer of 2-hydroxyethyl methacrylate (2-HEMA) and 2,3-Dihydroxypropyl Methacrylate (Glycerol Methacrylate, GMA). It consists of 46% hioxifilcon D and 54% water by weight when immersed in normal buffered saline solution. The lens is available in clear and with a blue visibility handling tint, phthalocyanato (2) - (copper). The hioxifilcon D 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 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 hydrophilic characteristics allow aqueous solutions to enter the lens and in its fully hydrated state the lens is approximately 54% water by weight. The physical properties of the lens are:

Refractive Index	1.408 (hydrated)
Light Transmission (clear)	greater than 95%
Light Transmission (tinted)	greater than 95%
Water Content	54 % ± 2%
Specific Gravity	1.137
Oxygen Permeability	23.0 X 10^{-11} (cm^2/sec) (ml O_2/ml x mm Hg @ 35°C), (revised Fatt method).

The **FireSoft-54G** lenses will be manufactured in spherical, toric and multifocal configurations with the following features.

• Chord Diameter	12.0 mm to 16.00 mm
• Center Thickness	0.01 mm to 0.50 mm
• Base Curve	8.0 mm to 9.5 mm
• Power Range	-20.00D to +20.00D in 0.25 steps
• Cylinder Power (Toric)	-0.25D to -10.00D
• Add Power (Multifocal)	+0.50D to +3.00D

ALL **FireSoft** Soft Contact Lenses are supplied sterile in vials containing a buffered saline solution. Vial labeling is printed with appropriate name, 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.

Intended Use:

The **FireSoft-SiHy** sphere (efrofilcon A) Soft Contact Lenses for daily wear are indicated for the correction of visual acuity in aphakic and not aphakic persons with non-diseased eyes with myopia or hyperopia. 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 **FireSoft-SiHy** toric (efrofilcon A) Soft Contact Lenses for daily wear are indicated for the correction of visual acuity in aphakic and not aphakic persons with non-diseased eyes with myopia or hyperopia and/or possesses refractive astigmatism not exceeding 12 diopters.

The **FireSoft-SiHy** multifocal (efrofilcon A) Soft Contact Lenses for daily wear are indicated for the correction of visual acuity in aphakic and not aphakic persons with non-diseased eyes with myopia or hyperopia and are presbyopic requiring add power of up to +4.00 diopters.

The **FireSoft-SiHy** multifocal toric (efrofilcon A) Soft Contact Lenses for daily wear are indicated for the correction of ametropia (myopia and hyperopia) in aphakic and not 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 **FireSoft-IC** (efrofilcon A) Soft Contact Lenses for daily wear are indicated for 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.

The **FireSoft-55** sphere (methafilcon A) Soft Contact Lenses for daily wear are indicated for the correction of visual acuity in aphakic and not aphakic persons with non-diseased eyes with myopia or hyperopia. 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 **FireSoft-55** toric (methafilcon A) Soft Contact Lenses for daily wear are indicated for the correction of visual acuity in aphakic and not aphakic persons with non-diseased eyes with myopia or hyperopia and/or possesses refractive astigmatism not exceeding 12 diopters.

The **FireSoft-55** multifocal (methafilcon A) Soft Contact Lenses for daily wear are indicated for the correction of visual acuity in aphakic and not aphakic persons with non-diseased eyes with myopia or hyperopia and are presbyopic requiring add power of up to +4.00 diopters.

The **FireSoft-55** multifocal toric (methafilcon A) Soft Contact Lenses for daily wear are indicated for the correction of ametropia (myopia and hyperopia) in aphakic and not 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 **FireSoft-49G** sphere (hioxifilcon B) Soft Contact Lenses for daily wear are indicated for the correction of visual acuity in aphakic and not aphakic persons with non-diseased eyes with myopia or hyperopia. 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**FireSoft-49G** toric (hioxifilcon B) Soft Contact Lenses for daily wear are indicated for the correction of visual acuity in aphakic and not aphakic persons with non-diseased eyes with myopia or hyperopia and/or possesses refractive astigmatism not exceeding 12 diopters.

The**FireSoft-49G** multifocal (hioxifilcon B) Soft Contact Lenses for daily wear are indicated for the correction of visual acuity in aphakic and not aphakic persons with non-diseased eyes with myopia or hyperopia and are presbyopic requiring add power of up to +4.00 diopters.

The **FireSoft-49G** multifocal toric (hioxifilcon B) Soft Contact Lenses for daily wear are indicated for the correction of ametropia (myopia and hyperopia) in aphakic and not 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 **FireSoft-54G** sphere (hioxifilcon D) Soft Contact Lenses for daily wear are indicated for the correction of visual acuity in aphakic and not aphakic persons with non-diseased eyes with myopia or hyperopia. 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 **FireSoft-54G** toric (hioxifilcon D) Soft Contact Lenses for daily wear are indicated for the correction of visual acuity in aphakic and not aphakic persons with non-diseased eyes with myopia or hyperopia and/or possesses refractive astigmatism not exceeding 12 diopters.

The **FireSoft-54G** multifocal (hioxifilcon D) Soft Contact Lenses for daily wear are indicated for the correction of visual acuity in aphakic and not aphakic persons with non-diseased eyes with myopia or hyperopia and are presbyopic requiring add power of up to +4.00 diopters.

The **FireSoft-54G** multifocal toric (hioxifilcon D) Soft Contact Lenses for daily wear are indicated for the correction of ametropia (myopia and hyperopia) in aphakic and not 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.

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.

Testing:

Non-clinical Testing

A series of in vitro and in vivo preclinical toxicology and biocompatibility tests were performed to assess the safety and effectiveness of the **FireSoft-SiHy (efrofilcon A), FireSoft-55 (methafilcon A), Firesoft-49G (hioxifilcon B) and Firesoft-54G (hioxifilcon D)** Soft Contact Lenses packaged in glass vials. All non-clinical toxicology tests were conducted in accordance with the GLP regulation. All other testing was conducted according to valid scientific protocols.

Test results of the non-clinical testing on the **FireSoft** Soft Contact Lenses demonstrate that:

- Lenses supplied in glass vials are sterile for the indicated shelf-life,
- The packaging material and extracts are not toxic and not irritating, and
- Lens physical and material properties are consistent with currently marketed lenses.

Clinical Data

The clinical performance of the (efrofilcon A) (methafilcon A) (hioxifilcon B) (hioxifilcon D) contact lens materials have been previously established, and therefore was not required for this 510(k).

The **FireSoft-SiHy** and **FireSoft-IC** (efrofilcon A) Silicone Hydrogel Daily Wear Soft Contact Lenses are identical and have the same manufacturing process (lathe-cut) to the cleared Intelliwave[3] (efrofilcon A) Silicone Hydrogel Daily Wear Soft Contact Lens cleared under K100221.

The **FireSoft-55,** (methafilcon A) Hydrogel Daily Wear Soft Contact Lens is identical and has the same manufacturing process (lathe-cut) to the cleared Contaflex-55 (methafilcon A) Hydrogel Daily Wear Soft Contact Lens cleared under K023989.

The **FireSoft-49G,** (hioxifilcon B) Hydrogel Daily Wear Soft Contact Lens is identical and has the same manufacturing process (lathe-cut) to the cleared Alden HP49 (hioxifilcon B) Hydrogel Daily Wear Soft Contact Lens cleared under K981252.

The **FireSoft-54G,** (hioxifilcon D) Hydrogel Daily Wear Soft Contact Lens is identical and has the same manufacturing process (lathe-cut) to the cleared Alden HP54 (hioxifilcon D) Hydrogel Daily Wear Soft Contact Lens cleared under K091327.

Conclusions Drawn from Studies

Validity of Scientific Data

Several laboratories under Good Laboratory Practice regulations conducted toxicology studies, Microbiology, chemistry, shelf-life stability studies and followed 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 **FireSoft-SiHy, FireSoft-IC, FireSoft-55, FireSoft-49G and FireSoft-54G** Daily Wear Soft Contact Lenses are as safe and effective as the predicate devices when used in accordance with the labeled directions for use and for the requested indication.

Risks and Benefits

The risks of the subject devices are the same as those normally attributed to the wearing of Daily Wear Soft Contact Lenses. The benefits to the patient are the same as those for other Daily Wear Soft Contact Lenses.

Substantial Equivalence:

The following matrix illustrates the functionality, indication for use, production method, FDA group#, USAN name and material characteristics of the **FireSoft-SiHy, FireSoft-IC, FireSoft-55, FireSoft-49G, FireSoft-54G** Daily Wear Soft Contact Lenses, as well as the predicate devices.

	FireSoft-SiHy New Device	IntelliWave3 (efrofilcon A) predicate device, K100221	FireSoft-55 New Device	Contaflex-55 (methafilcon A) predicate device, K023989	FireSoft-49G New Device	Alden HP49 (hioxifilcon B) predicate device, K981252	FireSoft-54G New Device	Alden HP54 (hioxifilcon D) predicate device, K091327	FireSoft-IC New Device	Soft K (efrofilcon A) predicate device, K122220
Functionality	same as predicate device	The contact lenses act as a refractive medium that focus light rays from near and distant objects on the retina.	same as predicate device	The contact lenses act as a refractive medium that focus light rays from near and distant objects on the retina.	same as predicate device	The contact lenses act as a refractive medium that focus light rays from near and distant objects on the retina.	same as predicate device	The contact lenses act as a refractive medium that focus light rays from near and distant objects on the retina.	same as predicate device	The contact lenses act as a refractive medium that focus light rays from near and distant objects on the retina.
Indications	same as predicate device	Daily wear, Silicone Hydrogel Soft (hydrophilic) contact lens	same as predicate device	Daily wear, Soft (hydrophilic) contact lens	same as predicate device	Daily wear, Soft (hydrophilic) contact lens	same as predicate device	Daily wear, Soft (hydrophilic) contact lens	same as predicate device	Daily wear, Silicone Hydrogel Soft (hydrophilic) contact lens
Production Method	Lathe-Cut, Customized RX	Lathe-Cut, Customized RX	Lathe-Cut, Customized RX	Lathe-Cut, Customized RX	Lathe-Cut, Customized RX	Lathe-Cut, Customized RX	Lathe-Cut, Customized RX	Lathe-Cut, Customized RX	Lathe-Cut, Customized RX	Lathe-Cut, Customized RX
FDA Group #	Group # V (Silicone Hydrogel) > 50% Water, Nonionic Polymers	Group # V (Silicone Hydrogel) > 50% Water, Nonionic Polymers	Group # II > 50% Water, Nonionic Polymers	Group # II > 50% Water, Nonionic Polymers	Group # II > 50% Water, Nonionic Polymers	Group # II > 50% Water, Nonionic Polymers	Group # II > 50% Water, Nonionic Polymers	Group # II > 50% Water, Nonionic Polymers	Group # V (Silicone Hydrogel) > 50% Water, Nonionic Polymers	Group # V (Silicone Hydrogel) > 50% Water, Nonionic Polymers
USAN name	efrofilcon A	efrofilcon A	methafilcon A	methafilcon A	hioxifilcon B	hioxifilcon B	hioxifilcon D	hioxifilcon D	efrofilcon A	efrofilcon A
Water Content	74%	74%	55%	55%	49%	49%	54%	54%	74%	74%
Oxygen Permeability	60 x 10-11 (cm2/sec) (ml O2/ml x mm Hg @ 35 degrees C), (revised Fatt method).	60 x 10-11 (cm2/sec) (ml O2/ml x mm Hg @ 35 degrees C), (revised Fatt method).	19.6 x 10-11 (cm2/sec) (ml O2/ml x mm Hg @ 35 degrees C), (revised Fatt method).	19.6 x 10-11 (cm2/sec) (ml O2/ml x mm Hg @ 35 degrees C), (revised Fatt method).	15 x 10-11 (cm2/sec) (ml O2/ml x mm Hg @ 35 degrees C), (revised Fatt method).	15 x 10-11 (cm2/sec) (ml O2/ml x mm Hg @ 35 degrees C), (revised Fatt method).	23 x 10-11 (cm2/sec) (ml O2/ml x mm Hg @ 35 degrees C), (revised Fatt method).	23 x 10-11 (cm2/sec) (ml O2/ml x mm Hg @ 35 degrees C), (revised Fatt method).	60 x 10-11 (cm2/sec) (ml O2/ml x mm Hg @ 35 degrees C), (revised Fatt method).	60 x 10-11 (cm2/sec) (ml O2/ml x mm Hg @ 35 degrees C), (revised Fatt method).
Specific Gravity	1.139	1.139	1.067	1.067	1.136	1.136	1.140	1.140	1.139	1.139

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

June 11, 2014

Firestone Optics, Inc.
c/o Mr. Martin Dalsing
Official Correspondent
806 Kimball Avenue
Grand Junction, CO 81501

Re: K133403
Trade/Device Name: FireSoft-SiHy (efrofilcon A) Silicone Hydrogel (Spherical, Toric, Multifocal, Multifocal Toric);
FireSoft-IC (efrofilcon A) Silicone Hydrogel (Irregular Cornea, Keratoconus, Post Graft);
FireSoft-55 (methafilcon A) Hydrogel (Spherical, Toric, Multifocal, Multifocal Toric);
FireSoft-49G (hioxifilcon B) Hydrogel (Spherical, Toric, Multifocal, Multifocal Toric);
FireSoft-54G (hioxifilcon D) Hydrogel (Spherical, Toric, Multifocal, Multifocal Toric).
Regulation Number: 21 CFR 886.5925
Regulation Name: Soft (hydrophilic) contact lens
Regulatory Class: Class II
Product Code: LPL
Dated: May 6, 2014
Received: May 7, 2014

Dear Mr. Dalsing,

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Deborah L. Falls -S

for Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic and Ear, Nose
and Throat Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K133403

Device Name
FireSoft-54G (hioxifilcon D) Hydrogel (Spherical, Toric, Multifocal, Multifocal Toric)

Indications for Use *(Describe)*
The FireSoft-54G sphere (hioxifilcon D) Soft Contact Lenses for daily wear are indicated for the correction of visual acuity in aphakic and not aphakic persons with non-diseased eyes with myopia or hyperopia. 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 FireSoft-54G toric (hioxifilcon D) Soft Contact Lenses for daily wear are indicated for the correction of visual acuity in aphakic and not aphakic persons with non diseased eyes with myopia or hyperopia and/or possesses refractive astigmatism not exceeding 12 diopters.
The FireSoft-54G multifocal (hioxifilcon D) Soft Contact Lenses for daily wear are indicated for the correction of visual acuity in aphakic and not aphakic persons with non diseased eyes with myopia or hyperopia and are presbyopic requiring add power of up to +4.00 diopters.
The FireSoft-54G multifocal toric (hioxifilcon D) Soft Contact Lenses for daily wear are indicated for the correction of ametropia (myopia and hyperopia) in aphakic and not 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.
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)

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K133403

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K133403

Device Name
FireSoft-49G (hioxifilcon B) Hydrogel (Spherical, Toric, Multifocal, Multifocal Toric)

Indications for Use *(Describe)*
The FireSoft-49G sphere (hioxifilcon B) Soft Contact Lenses for daily wear are indicated for the correction of visual acuity in aphakic and not aphakic persons with non-diseased eyes with myopia or hyperopia. 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.
TheFireSoft-49G toric (hioxifilcon B) Soft Contact Lenses for daily wear are indicated for the correction of visual acuity in aphakic and not aphakic persons with non diseased eyes with myopia or hyperopia and/or possesses refractive astigmatism not exceeding 12 diopters.
TheFireSoft-49G multifocal (hioxifilcon B) Soft Contact Lenses for daily wear are indicated for the correction of visual acuity in aphakic and not aphakic persons with non diseased eyes with myopia or hyperopia and are presbyopic requiring add power of up to +4.00 diopters.
The FireSoft-49G multifocal toric (hioxifilcon B) Soft Contact Lenses for daily wear are indicated for the correction of ametropia (myopia and hyperopia) in aphakic and not 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.
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)

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K133403

Device Name
FireSoft IC (efrofilcon A) Silicone Hydrogel (Irregular Cornea, Keratoconus, Post Graph)

Indications for Use *(Describe)*
The FireSoft-IC (efrofilcon A) Soft Contact Lenses for daily wear are indicated for 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)

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K133403

Device Name
FireSoft SiHy (efrofilcon A) Silicone Hydrogel (Spherical, Toric, Multifocal, Multifocal Toric)

Indications for Use *(Describe)*
The FireSoft-SiHy sphere (efrofilcon A) Soft Contact Lenses for daily wear are indicated for the correction of visual acuity in aphakic and not aphakic persons with non-diseased eyes with myopia or hyperopia. 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 FireSoft-SiHy toric (efrofilcon A) Soft Contact Lenses for daily wear are indicated for the correction of visual acuity in aphakic and not aphakic persons with non diseased eyes with myopia or hyperopia and/or possesses refractive astigmatism not exceeding 12 diopters.
The FireSoft-SiHy multifocal (efrofilcon A) Soft Contact Lenses for daily wear are indicated for the correction of visual acuity in aphakic and not aphakic persons with non diseased eyes with myopia or hyperopia and are presbyopic requiring add power of up to +4.00 diopters.
The FireSoft-SiHy multifocal toric (efrofilcon A) Soft Contact Lenses for daily wear are indicated for the correction of ametropia (myopia and hyperopia) in aphakic and not 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.
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)

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Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K133403

Device Name
FireSoft 55 (methafilcon A) Hydrogel (Spherical, Toric, Multifocal, Multifocal Toric)

Indications for Use *(Describe)*
The FireSoft-55 sphere (methafilcon A) Soft Contact Lenses for daily wear are indicated for the correction of visual acuity in aphakic and not aphakic persons with non-diseased eyes with myopia or hyperopia. 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 FireSoft-55 toric (methafilcon A) Soft Contact Lenses for daily wear are indicated for the correction of visual acuity in aphakic and not aphakic persons with non diseased eyes with myopia or hyperopia and/or possesses refractive astigmatism not exceeding 12 diopters.
The FireSoft-55 multifocal (methafilcon A) Soft Contact Lenses for daily wear are indicated for the correction of visual acuity in aphakic and not aphakic persons with non diseased eyes with myopia or hyperopia and are presbyopic requiring add power of up to +4.00 diopters.
The FireSoft-55 multifocal toric (methafilcon A) Soft Contact Lenses for daily wear are indicated for the correction of ametropia (myopia and hyperopia) in aphakic and not 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.
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)

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