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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:

K121324

**Applicant information:**

Date Prepared: April 25, 2012

Name: **Advanced Vision Technologies**  
Address: 14828 West 6<sup>th</sup> Avenue, Suite 15B  
Golden, CO 80401

Contact Person: Mr. Keith Parker  
President

Phone number: (303) 384 1111

Consultant: Martin Dalsing  
Medvice Consulting, Inc.  
806 Kimball Avenue  
Grand Junction, CO 81501

Phone number (970) 243-5490

**Device Information:**

Device Classification: Class II

Classification Number: LPL

Classification Name: Lenses, Soft Contact, Daily Wear

Trade Name: **AVT NaturaSoft, Definitive Silicone Hydrogel Daily Wear  
Soft Contact Lens (efrofilcon A)**

# Advanced Vision Technologies

510(k) Premarket Notification

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## Equivalent Devices:

The AVT NATURASOFT, Definitive Silicone Hydrogel Daily Wear Soft Contact Lenses (efrofilcon A) are substantially equivalent to the following predicate devices:

### *Predicate devices:*

**“IntelliWave<sup>3</sup>”, Silicone Hydrogel Daily Wear Soft Contact Lens (efrofilcon A)”**  
by Art Optical Contact Lens, Inc.  
510(k) number: **K100221**

**“Biofinity (comfilcon A)”**  
by Coopervision, Inc.  
510(k) number; **K052560**

**“ActiFresh 400 (lidofilcon A)”**  
By Hydron Ltd.  
510(k) number: **K983637**

## Device Description:

The AVT NATURASOFT 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 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 custom RX. It consists of 26% efrofilcon A and 74% water by weight when immersed in a 0.9% 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.

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The Physical properties of the lens are:

<b>Refractive Index</b>	1.38
<b>Light Transmission</b>	greater than 97%
<b>Surface Character</b>	hydrophilic
<b>Water Content</b>	74 %
<b>Specific Gravity</b>	1.048 (hydrated)
<b>Oxygen Permeability</b>	$59.8 \times 10^{-11}$ (cm <sup>2</sup> /sec) (ml O <sub>2</sub> /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, multifocal toric 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 -12.00D
- Cylinder Power (Multifocal Toric) -0.25D to -4.00D
- Add Power (Multifocal) +0.50D to +4.00D

The lens is supplied sterile in vials containing a 0.9% 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.

## Intended Use:

The **AVT NATURASOFT**, 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 **AVT NATURASOFT**, 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 **AVT NATURASOFT**, 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.

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The **AVT NATURASOFT**, 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 **AVT NATURASOFT**, 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.

### 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 **AVT NATURASOFT** (efofilcon A) Silicone Hydrogel 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 **AVT NATURASOFT** (efofilcon A) Silicone Hydrogel 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 (efofilcon A) lens material has been previously established, and therefore was not required for this 510(k).

The **AVT NATURASOFT**, (efofilcon A) Silicone Hydrogel Daily Wear Soft Contact Lens is identical to the cleared Intelliwave<sup>3</sup> (efofilcon A) Silicone Hydrogel Daily Wear Soft Contact Lens, cleared under K100221.

The **AVT NATURASOFT**, (efofilcon A) Silicone Hydrogel Daily Wear Soft Contact Lenses have the identical manufacturing process (lathe-cut versus lathe-cut) as the marketed Intelliwave<sup>3</sup> (efofilcon A) Silicone Hydrogel Daily Wear Soft Contact Lens, cleared under K100221.

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## Substantial Equivalence:

The following matrix illustrates the production method, lens function and material characteristics of the AVT NATURASOFT, (efrofilcon A) Silicone Hydrogel Daily Wear Soft Contact Lens, as well as the predicate devices.

## 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 AVT NATURASOFT, (efrofilcon A) Silicone Hydrogel Daily Wear Soft Contact Lens is as safe and effective as the predicate device when used in accordance with the labeled directions for use and for the requested indication.

### Risks and Benefits

The risks of the subject device are the same as those normally attributed to the wearing of Silicone Hydrogel, Daily Wear Soft Contact Lens. The benefits to the patient are the same as those for other Silicone Hydrogel contact lenses.

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Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Room -WO66-G609  
Silver Spring, MD 20993-0002

Advanced Vision Technologies  
c/o Mr. Martin Dalsing  
Medvice Consulting, Inc.  
2214 Sanford Drive, Suite # B7  
Grand Junction, CO 81505

AUG 23 2012

Re: K121324

AVT NaturaSoft, Definitive Silicone Hydrogel Daily Wear Soft Contact Lens (efrofilcon A)  
Regulation Number: 21 CFR 886.5925  
Regulation Name: Lenses, Soft Contact, Daily Wear (Silicone Hydrogel)  
Regulatory Class: Class II  
Product Code: LPL  
Dated: August 10, 2012  
Received: August 14, 2012

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](#).

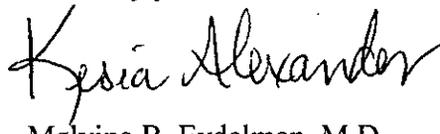
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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,



 Malvina B. Eydelman, M.D.  
Director  
Division of Ophthalmic, Neurological,  
and Ear, Nose and Throat Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

## INDICATIONS FOR USE STATEMENT

510(k):                   K121324

Device Name:           AVT NATURASOFT, Definitive Silicone Hydrogel Daily Wear Soft Contact Lens (efofilcon A)

### INDICATIONS FOR USE:

The AVT NATURASOFT, sphere (efofilcon A) Silicone Hydrogel 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 AVT NATURASOFT, toric (efofilcon A) Silicone Hydrogel 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 AVT NATURASOFT, multifocal (efofilcon A) Silicone Hydrogel 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 AVT NATURASOFT, 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 AVT NATURASOFT, irregular cornea (efofilcon A) Silicone Hydrogel 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 are to prescribe the lenses for quarterly 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.

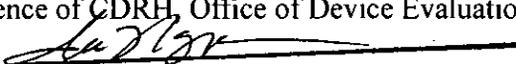
Prescription Use   
(Per 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use   
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

  
(Division Sign-Off)

Division of Ophthalmic, Neurological and Ear,  
Nose and Throat Devices

510(k) Number           K121324