FEB - 1 2005

K043540

Traditional 510(k)-Submission

8.0 Summary of Safety and Effectiveness

1.0 Name and address of submitter

Westcon Contact Lens Company, Inc.
611 Eisenhauer Street
Grand Junction, CO. 81503

Contact Person Carol Noble
970-245-3845
Fax 970-245-4516

Date Prepared 12/20/04

2.0 Name of Device

- **Trade Name**: Horizon 59 Oasis (hioxifilcon A)
- **Common Name**: Daily Wear Soft Contact Lens
- **Generic (USAN) Name**: Hioxifilcon A
- **Classification Name**: Soft Hydrophilic Contact Lens

3.0 Indications

Horizon 59 Oasis (hioxifilcon A) **Spherical,** Horizon 59 Oasis (hioxifilcon A) **Toric,** Horizon 59 Oasis (hioxifilcon A) **Bi-con,** Horizon 59 Oasis (hioxifilcon A) **Bi-con Toric,** Horizon 59 Oasis (hioxifilcon A) **Progressive,** Horizon 59 Oasis (hioxifilcon A) **Progressive Toric** are indicated for daily wear for the correction of refractive ametropia (myopia, hyperopic, astigmatism and presbyopia) in aphakic or not-aphakic persons with nondiseased eyes.
The color-enhanced version is indicated for daily wear to enhance or alter the apparent eye color.
The lenses may be disinfected using chemical systems only.

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4.0 Device Description

The soft contact lenses that are manufactured from Hioxifilcon A lens blanks are lathe cut into a hemispherical shell that are designed to fit over the corneal surface of the eye. These lenses are designed with varying base curves that conform to the shape of the radius of the cornea and center over the apex of the cornea to provide correction of refractive ametropia (myopia, hyperopic, astigmatism and presbyopia) in aphakic or not-aphakic persons with nondiseased eyes.

Each lens is designed with a base curve on the internal side of the lens and an optical zone in the center of the lens, generally of a diameter greater than 6 mm. The primary and secondary curves as well as beveled edge configurations are built into the lens for the purpose of aiding on the lens centration and comfort.

Adding color enhancement to the surface of the lens modifies the clear version of the Horizon 59 Oasis (hioxifilcon A) contact lens. The tinting process alters or changes the lens by affixing a listed color reactive additive on that portion of the anterior (front) surface of the lens that corresponds to the iris. The color additives are used in the amounts not to exceed the minimum reasonably required to accomplish the intended coloring effect. The practitioner may also choose tint intensity and custom mix colors.

The Horizon 59 Oasis (hioxifilcon A) lenses are available in shades of the following: blue, green, brown and aqua.

Combining one or more reactive colors additives with distilled water forms the color enhancement. The reactive color additives that may be used either alone or in combination are: Reactive Blue 19, Reactive Black 5, Reactive Red 11, Reactive Orange 78, Reactive Yellow 15, Reactive Red 180.

5.0 Substantially Equivalent To:

Westcon will be claiming equivalency to our own that is currently FDA approved in 510(k) K031774.

6.0 Summary of Safety and Effectiveness

The Horizon lenses were subjected to leachability studies and showed no identifiable evidence of tint pigment leaching.

7.0 Technical Summaries

7.1 Toxicology:

Cytotoxicity, systemic toxicity and ocular irritation studies were. Test results showed no evidence of cellular or systemic toxicity, or ocular irritation.

8.0 Summary of Safety and Effectiveness

7.2 Physical/Optical Characteristics

Light transmittance, linear expansion and radial expansion were determined. A comparison of data from these studies showed that the Horizon 59 Oasis (hioxifilcon A) is equivalent in physical and optical characteristics as 510(k) K031774.

7.3 Microbiology

There will be no changes to the validated process in 510(k) K954524

7.4 Compatibility

The spectra measurement after the numerous cleaning and disinfecting cycles remained the same as the before measurement.

7.5 The shelf life study has been started on color-enhanced lenses and will be completed in 2005 year. The procedure is based on the guidance documents Shelf Life of Medical Devices-April 1991 and Premarket Notification Guidance Document for Daily Wear Contact Lenses-May 1994.

The packaging remains the same as 510(k) K954524.

8.0 Conclusion

In conclusion, it is Westcon's conviction that the data submitted shows the Horizon 59 Oasis (hioxifilcon A) contact lens does not raise different questions of safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB - 1 2005

Westcon Contact Lens Co., Inc.
c/o Ms. Carol Noble
611 Eisenhauer St.
Grand Junction, CO 81505

Re: K043540
Trade/Device Name: Horizon 59 Oasis (Hioxifilcon A) Daily Wear Contact Lenses
Regulation Number: 21 CFR 886.5925
Regulation Name: Daily Wear Soft Contact Lens
Regulatory Class: Class II
Product Code: LPL
Dated: December 20, 2004
Received: December 22, 2004

Dear Ms. Noble:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4613. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

A. Ralph Rosenthal, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

5.0 INDICATIONS FOR USE STATEMENT

Device Name:

Horizon 59 Oasis (hioxifilcon A) **Spherical,** Horizon 59 Oasis (hioxifilcon A) **Toric,** Horizon 59 Oasis (hioxifilcon A) **Bi-con,** Horizon 59 Oasis (hioxifilcon A) **Bi-con Toric,** Horizon 59 Oasis (hioxifilcon A) **Progressive,** Horizon 59 Oasis (hioxifilcon A) **Progressive Toric**

Indication of Use:

Horizon 59 Oasis (hioxifilcon A) **Spherical,** Horizon 59 Oasis (hioxifilcon A) **Toric,** Horizon 59 Oasis (hioxifilcon A) **Bi-con,** Horizon 59 Oasis (hioxifilcon A) **Bi-con Toric,** Horizon 59 Oasis (hioxifilcon A) **Progressive,** Horizon 59 Oasis (hioxifilcon A) **Progressive Toric** are indicated for daily wear for the correction of refractive ametropia (myopia, hyperopic, astigmatism and presbyopia) in aphakic or not-aphakic persons with nondiseased eyes.
The color-enhanced version is indicated for daily wear to enhance or alter the apparent eye color.
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(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter Use _____
(Per 21 CFR 801.109)
(Optional Format 1-2-96)

(Division Sign-Off)
Division of Ophthalmic Ear, Nose and Throat Devises

510(k) Number K043540