

8.0 510 (k) Safety and Effectiveness Summary

1.0 Name and address of submitter Westcon Contact Lens Company, Inc.
611 Eisenhower Street
Grand Junction, CO. 81503

Contact Person Carol Noble
970-245-3845
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Date Prepared 6/5/99

2.0 Name of Device◆ **Trade Name:**

W-55 (methafilcon A) Clear and Visibility Tinted Lens Blank and Horizon 55 Soft (Clear) and Horizon 55 Westint (tinted).

◆ **Common Name:** Daily Wear Soft Contact Lens

◆ **Generic (USAN) Name:** Methafilcon A

◆ **Classification Name:** Soft Hydrophilic Contact Lens

3.0 Indications

Horizon 55 Soft (methafilcon A) Spherical (hydrophilic) contact lenses in **clear** or with **blue visibility tint** are indicated for daily wear. The lenses are indicated for the correction of visual acuity in non-aphakic patients with non-diseased eyes myopic, hyperopic. The spherical lenses are being applied from +20.00 to -20.00 diopters and masking up to 1.50 diopters of astigmatism where it does not interfere with visual acuity.

Horizon 55 Soft (methafilcon A) Toric soft (hydrophilic) contact lenses in **clear** or with **blue visibility tint** are indicated for daily wear. The lenses are indicated for the correction of visual acuity in non-aphakic patients with non-diseased eyes that are myopic, hyperopic or astigmatic. The toric lenses are being applied for spherical powers from +20.00 to -20.00 diopters and masking up to 10.00 diopters of astigmatism where it does not interfere with visual acuity.

Horizon 55 Bi-con (methafilcon A) Spherical soft (hydrophilic) contact lenses in **clear** or with **blue visibility tint** are indicated for daily wear. The lenses are indicated for the correction of visual acuity in non-aphakic patients with non-diseased eyes myopic, hyperopic and are presbyopic. The spherical lenses are being applied from +20.00 to -20.00 diopters and masking up to 1.00 diopters of astigmatism where it does not interfere with visual acuity.

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Horizon 55 Bi-con (methafilcon A) **Toric** soft (hydrophilic) contact lenses in **clear** or with **blue visibility tint** are indicated for daily wear. The lenses are indicated for the correction of visual acuity in non-aphakic patients with non-diseased eyes myopic, hyperopic possess refractive astigmatism not exceeding 4.00 diopters and are presbyopic. The spherical lenses are being applied from +20.00 to -20.00 diopters and masking up to 10.00 diopters of astigmatism where it does not interfere with visual acuity.

4.0 Device Description

W-55 (methafilcon A) clear or tinted lens blanks are a hydrophilic polymer of 2-hydroxyethyl methacrylate cross linked with ethyleneglycol dimethacrylate. The lens consists of 45% methafilcon and 55% water by weight when immersed in buffered saline solution. When the lens blank is tinted blue, up to .8 % of the color additive Copper Phthalocyanine Blue Pigment will be added to the MA. The color additive conforms to 21 CFR Part 74.3045.

The soft contact lenses that are manufactured from W-55 lens blanks, **clear** or **tinted**, can be lathe cut into a hemispherical shell which are designed to fit over the corneal surface of the eye. These lenses are designed with varying base curves which conform to the shape of the radius of the cornea and center over the apex of the cornea to provide corrective myopia (nearsightedness), hyperopia (farsightedness), and astigmatism (multifocal). Each lens provides corrective power, which corresponds to the refractive power of the eye to which it is being treated.

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 Secondary and tertiary curves as well as beveled edge configurations are built into the lens for the purpose of aiding on the lens centration and comfort.

5.0 Substantially Equivalent To:

Westcon will be claiming equivalency to our own contact lenses that are currently FDA approved in 510(k) K954524

6.0 Summary of Safety and Effectiveness

W-55 (methafilcon A) lens blank with visibility tint were subjected to extraction studies and showed no identifiable evidence of tint pigment leeching.

7.0 Technical Summaries

7.1 Toxicology:

Cytotoxicity, systemic toxicity and ocular irritation studies were conducted with samples of tinted lenses. Test results showed no evidence of cellular or systemic toxicity, or ocular irritation.

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7.2 Physical/Optical Characteristics

Light transmittance, refractive index, water content, linear expansion, radial expansion and tensile strength were determined in samples of tinted lenses. A comparison of data from this study showed that the tinted lenses were equivalent in physical and optical characteristics as 510(k) K954524

7.3 Microbiology

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

7.4 Compatibility

Westcon ran non-clinical studies for the clear lenses in 1995 in 510(k) K954524 and for the visibility-tinted lenses in 1998 (submitted with this notification). At the end of the 30 cycles all lenses were within normal limits.

7.5 Shelf Life

The shelf life studies have been started on visibility tinted lenses and will be completed later this 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.

Westcon will utilize a 10-year expiration date on the actual button as in 510(k) K954524.

8.0 Conclusion

In conclusion, it is Westcons conviction that the data submitted shows that by adding the tint does not raise different questions of safety and effectiveness.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 29 1999

Ms. Carol Noble
Management Representative
Westcon Contact Lens Company, Inc.
611 Eisenhower Street
Grand Junction, Co 81505

Re: K992010
Trade Name: W-55 (methafilcon A) Clear and Visibility Tinted Lens Blank and
Horizon 55 Soft (Clear) and Horizon 55 Westint (tinted)
Regulatory Class: II
Product Code: 86 LPL
Dated: June 9, 1999
Received: June 15, 1999

Dear Ms. Noble:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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.

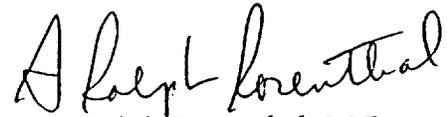
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

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This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,



A. Ralph Rosenthal, M.D.

Director

Division of Ophthalmic Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

5.0 INDICATIONS FOR USE STATEMENT

Device Name:

Horizon 55 Soft and Horizon 55 Westint (methafilcon A) Soft (Spherical & Toric) Daily Wear Contact Lens.

W-55 (methafilcon A) lens blanks, clear or tinted.

Indication of Use:

The **Horizon 55 Westint and Horizon 55 (methafilcon A) Soft (hydrophilic) Contact Lenses** for daily wear are indicated for the correction of visual acuity in non aphakic persons with non-diseased eyes with myopia or hyperopia.

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

_____ Concurrency of CDRH, Office of Device Evaluation (ODE)

Prescription Use x
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____

(Optional Format 1-2-96)

James W. C. Brown, Ph.D.

(Division Sign-Off)
Division of Ophthalmic Devices

510(k) Number K992010