

K080794

510(k) Summary

Submitter Information:

PolyVue Distribution, Inc.
759 Appian Way
Pinole, California 94564

Contact Person: Garold L. Edwards

Telephone: (408) 221-3860
Fax: (831) 335-0166

Date Prepared: March 3, 2008

Device Name:

Common Name: Soft (Hydrophilic) Contact Lens
Trade/Proprietary Names: I-55 Single Vision (methafilcon A) Soft
(Hydrophilic) Contact Lens for Daily Wear

I-55 Toric (methafilcon A) Soft (Hydrophilic)
Contact Lens for Daily Wear

I-55 Multifocal (methafilcon A) Soft (Hydrophilic)
Contact Lens for Daily Wear

Classification Name: Soft (Hydrophilic) Contact Lens
Device Classification: Class II (21 CFR 886.5925)

Predicate Devices:

The molded Definition AC (methafilcon A) Soft (Hydrophilic) Contact Lens was selected as the predicate device.

Description of Devices:

I-55 Single Vision, I-55 Toric and I-55 Multifocal (methafilcon A) Soft (Hydrophilic) Daily Wear Contact Lenses are hemispherical flexible shells that cover the cornea and a portion of the adjacent sclera. The **I-55 Single Vision Contact Lens** is available in a single vision lens design, the **I-55 Toric Contact Lens** is available in a back surface design, and the **I-55 Multifocal Contact Lens** is available in a concentric aspheric lens design. The lens material (methafilcon A) is a hydrophilic co-polymer of 2-hydroxyethyl methacrylate (HEMA) and methacrylic acid, cross-linked with ethyleneglycol dimethacrylate (EGDMA), using AIBN as the

initiator. The lens contain 55% water by weight. I-55, I-55 Toric and I-55 Multifocal (methafilcon A) Soft (Hydrophilic) Contact Lenses for Daily Wear are visibility tinted using Pigment Blue 15, ([Phthalocyaninato(2-)] copper) which is approved for coloring contact lenses under 21 CFR § 74.3045.

Comparison to Predicate Devices

Lens type	<i>I-55 Single Vision, I-55 Toric and I-55 Multifocal (methafilcon A) Soft (Hydrophilic) Contact Lenses for Daily Wear</i>	<i>Definition AC (methafilcon A) Soft (Hydrophilic) Contact Lenses for Daily Wear</i>
Predicate device 510(k)		<i>K051095</i>
Material	methafilcon A	methafilcon A
Material classification	Hydrophilic Lens Group 1	Hydrophilic Lens Group 1
Indication for use	myopia, hyperopia, astigmatism and presbyopia	myopia, hyperopia, astigmatism and presbyopia
Water content	55%	55%
Visible light transmittance	99%	98%
Dk (35° C)	19.01×10^{-11}	18.86×10^{-11}
Powers	+20.00 to -20.00 Diopters	+20.00 to -20.00 Diopters
Color	blue visibility	blue visibility
Refractive Index	1.415	1.416
Specific gravity	1.039	1.030
Method of manufacture	Molded	Molded

Indications for Use:

The **I-55 Single Vision (methafilcon A) Soft (Hydrophilic) Contact Lens** is indicated for daily wear for the correction of refractive ametropia (myopia and hyperopia) in aphakic or not-aphakic persons with non-diseased eyes that may exhibit refractive and/or corneal astigmatism up to 2.00 diopters that does not interfere with visual acuity.

The **I-55 Toric (methafilcon A) Soft (Hydrophilic) Contact Lens** is indicated for daily wear for the correction of refractive ametropia (myopia, hyperopia and astigmatism) in aphakic and/or not aphakic persons with non-diseased eyes that may exhibit refractive and/or corneal astigmatism up to 5.00 Diopters.

The **I-55 Multifocal (methafilcon A) Soft (Hydrophilic) Contact Lens** is indicated for daily wear for the correction of refractive ametropia (myopia and hyperopia) and presbyopia in aphakic or not-aphakic persons with non-diseased eyes that may exhibit refractive and/or corneal astigmatism up to 2.00 diopters that does not interfere with visual acuity.

The lenses may be disinfected using chemical (not heat) or hydrogen peroxide disinfecting systems. Eyecare practitioners may prescribe the lenses for daily wear and/or frequent replacement.

Description of Safety and Substantial Equivalence:

A series of pre-clinical tests were performed to demonstrate the safety and effectiveness of **I-55 Single Vision, I-55 Toric, and I-55 Multifocal (methafilcon A) Soft (Hydrophilic) Contact Lenses for Daily Wear**, and to establish substantial equivalence to the predicate devices.

Results of Systemic Injection, Primary Ocular Irritation and Cytotoxicity Tests show the lenses to be non-toxic and non-irritating. I-55 lenses were extracted and evaluated for conformance to standards. Results showed no evidence of unacceptable levels of residues in the extracts. Physicochemical testing of I-55 lenses demonstrated equivalency to the predicate devices.

Conclusion:

Information submitted in the 510(k) establishes that **I-55 Single Vision, I-55 Toric and I-55 Multifocal (methafilcon A)** contact lenses have comparable physicochemical properties to the predicate devices and do not raise questions of safety and effectiveness. Shelf life testing has shown the lenses remain sterile and that lens properties do not change before the expiration date. Therefore, the devices are substantially equivalent to the predicate devices.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

PolyVue Distribution, Inc.
c/o Garold L. Edwards, OD, FAAO
7077 McAdams Lane
Felton, CA 95018

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 17 2008

Re: K080794

Trade/Device Name: I-55 Single Vision (methafilcon A) Soft (hydrophilic) Contact Lens for
Daily Wear
I-55 Toric (methafilcon A) Soft (hydrophilic) Contact Lens for Daily Wear
I-55 Multifocal (methafilcon A) Soft (hydrophilic) Contact Lens for
Daily Wear

Regulation Number: 21 CFR 886.5925

Regulation Name: Soft (hydrophilic) contact lens

Regulatory Class: Class II

Product Code: LPL

Dated: November 18, 2008

Received: November 21, 2008

Dear Dr. Edwards:

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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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 (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



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

Indications for Use

510(k) Number: K080794

Device Names:

I-55 Single Vision (methafilcon A) Soft (Hydrophilic) Contact Lens for Daily Wear

I-55 Toric (methafilcon A) Soft (Hydrophilic) Contact Lens for Daily Wear

I-55 Multifocal (methafilcon A) Soft (Hydrophilic) Contact Lens for Daily Wear

Indications for Use:

I-55 Single Vision (methafilcon A) Soft (Hydrophilic) Contact Lens for Daily Wear is indicated for daily wear for the correction of refractive ametropia (myopia and hyperopia) in aphakic or not aphakic persons with non-diseased eyes that may exhibit refractive and/or corneal astigmatism up to 2.00 Diopters that does not interfere with visual acuity.

I-55 Toric (methafilcon A) Soft (Hydrophilic) Contact Lens for Daily Wear is indicated for daily wear for the correction of refractive ametropia (myopia, hyperopia and astigmatism) in aphakic and not aphakic persons with non-diseased eyes that may exhibit refractive and/or corneal astigmatism up to 5.00 Diopters.

I-55 Multifocal (methafilcon A) Soft (Hydrophilic) Contact Lens for Daily Wear is indicated for daily wear for the correction of refractive ametropia (myopia and hyperopia) and presbyopia in aphakic or not aphakic persons with non-diseased eyes that may exhibit refractive and/or corneal astigmatism up to 2.00 Diopters that does not interfere with visual acuity.

The lenses may be disinfected using chemical (not heat) or hydrogen peroxide, disinfecting systems. Eyecare practitioners may prescribe the lenses for daily wear and/or frequent replacement.

Prescription Use ✓
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Ming-chuen Shi

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

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