K980818

510 (k) Summary

MAR 30 1998

SUBMITTER:

Submitted on behalf of:

Company Name:	Stephen A. Dunn, Inc.
Address:	1329 Lusitana Street Honolulu, HI 96813
Telephone:	(808) 599-2742
Fax:	(808) 521-2823

CONTACT PERSON: Martin S. Knopf

DATE SUMMARY PREPARED: February 27, 1998

TRADE NAME: The PolyVue Silver Chord, Unisoft (methafilcon A) Spherical, Aspherical, Toric and Multifocal Hydrophilic Contact Lenses for Daily Wear (clear and tinted

COMMON NAME: contact lens

SUBSTANTIALLY EQUIVALENT TO:

The PolyVue Silver Chord, Unisoft (methafilcon A) Spherical, Aspherical, Toric and Multifocal Hydrophilic Contact Lenses for Daily Wear (clear and tinted) is equivalent to PolyVue Silver Chord, Unisoft (methafilcon A) Spherical, Aspherical, and Toric Hydrophilic Contact Lenses for Daily Wear which received marketing clearance pursuant to K953807 as currently marketed in the U.S.

The PolyVue Silver Chord, Unisoft (methafilcon A) Spherical, Aspherical, Toric and Multifocal Hydrophilic Contact Lenses for Daily Wear (clear and tinted) are substantially equivalent to Stephen A. Dunn, Inc.'s currently marketed PolyVue Silver Chord, Unisoft (methafilcon A) Spherical, Aspherical, and Toric Hydrophilic Contact Lenses for Daily Wear. PolyVue Silver Chord, Unisoft (methafilcon A) Spherical, Aspherical, Toric and Multifocal Hydrophilic Contact Lens (clear and tinted) is the same lens material that Stephen A. Dunn, Inc. received marketing clearance pursuant to K953807. This lens conforms to and is substantially equivalent to spherical, aspherical, presbyopic and astigmatic lens designs that are currently marketed in the United States. The intended use and target population are substantially equivalent.

This lens is in Group 4 ionic, high water content polymers as established by the FDA and located in the Guidance Document for Daily Wear Contact Lenses, Revised Edition May 1994. The physical, optical, and chemical properties of the PolyVue Silver Chord, Unisoft (methafilcon A) Spherical, Aspherical, Toric and Multifocal Hydrophilic Contact Lenses for Daily Wear (clear and tinted) and the PolyVue Silver Chord, Unisoft (methafilcon A) Spherical, Aspherical, and Toric Hydrophilic Contact Lenses for Daily Wear which received marketing clearance pursuant to K953807 are substantially equivalent.

SIMILARITIES and DIFFERENCES:

PARAMETER	PolyVue Silver Chord, Unisoft (methafilcon A) Spherical, Aspherical, Toric and Multifocal Hydrophilic Contact Lenses for Daily Wear (clear and tinted)	PolyVue Silver Chord, Unisoft (methafilcon A) Spherical, Aspherical and Toric Hydrophilic Contact Lenses for Daily Wear
material	methafilcon A	methafilcon A
indication for use	myopia, hyperopia, presbyopia and astigmatism	myopia, hyperopia, presbyopia and astigmatism
water content	55%	55%
light transmittance	>95%	>95%
Dk (35°C)	18.83 X 10^{-11}	18.83 X 10^{-11}
powers	-20.00 to+20.00 D	-20.00 to+20.00 D
color	clear and green tinted	clear
Color additive used	Phthalocyanine Green	N/A
specific gravity	1.09	1.09
refractive index	1.415	1.415

DISCUSSION OF SIMILARITIES AND DIFFERENCES

The PolyVue Silver Chord, Unisoft (methafilcon A) Spherical, Aspherical, Toric and Multifocal Hydrophilic Contact Lenses for Daily Wear (clear and tinted) has the same intended use and target population as the company's referenced predicate device.

PolyVue Silver Chord, Unisoft (methafilcon A) Spherical, Aspherical, Toric and Multifocal Hydrophilic Contact Lenses for Daily Wear (clear and tinted) differs from some of the predicate devices characteristics with respect to the addition of an approved color additive and the additional, alternative manufacturing process. These issues will now be discussed in turn.

1. **Materials**
   methafilcon A. This is identical for both the subject and predicate device

2. **Biocompatibility**
   Identical, since the material is the same

3. **Labeling Compared to Predicate Labeling**

   Labeling for daily wear soft contact lenses has been provided by reference in the predicate application for Stephen A. Dunn, Inc., pursuant to K953807. The only modification to this labeling is the inclusion of the color additive, phthalocyanine green to the device description. This labeling follows the recommended labeling which is supplied in the Guidance Document for Daily Wear Soft Contact Lenses issued by FDA May 1994. Each of the labeling elements, the Vial Label, Package Insert, Professional Fitting and Information Guide and Patient Instruction Booklet.

4. Manufacturing Method

In a standard lathing process for a soft lens, the lenses are fully lathe cut from cast molded buttons. This is the currently cleared manufacturing method for the predicate lens. The subject lens will be either fully lathed from these buttons or may alternatively be manufactured from a molded button, which incorporates a molded base curve. The front surface will then be lathe cut. The process shall be validated to demonstrate that the finished product is equivalent to a standard lathe cut lens. Samples will be periodically taken to continually assure that the finished lens specifications are complied with.

DESCRIPTION of the DEVICE:

Soft contact lenses are hemispherical shells manufactured of polymerized material of HEMA and methacrylic acid crosslinked with EGDMA, which yield the appearance of lenses, 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 refraction of functional conditions of the eye including myopia (nearsightedness), hyperopia (farsightedness), presbyopia and astigmatism (multiple foci). Each lens provides corrective power, which is to correspond 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 which is generally of a diameter greater than 6mm. Spherical and aspheric curves as well as beveled edge configurations are built into the lens for aiding in lens centration and comfort as well as providing additional add power for near and blocking spherical aberration.

INDICATIONS FOR USE:

Device Name: PolyVue Silver Chord, Unisoft (methafilcon A) Spherical, Aspherical, Toric and Multifocal Hydrophilic Contact Lens (clear and tinted

The PolyVue Silver Chord, Unisoft (methafilcon A) Spherical, Aspherical, Toric and Multifocal Hydrophilic Contact Lens (clear and tinted) is indicated for daily wear for the correction of refractive ametropia (myopia and hyperopia), presbyopia and astigmatism in not-aphakic persons with non-diseased eyes.

Eyecare practitioners may prescribe the lens for daily wear in a Frequent Replacement Program. The lenses may be disinfected using heat, chemical or hydrogen peroxide disinfection systems.

PARAMETERS AVAILABLE:

PolyVue Silver Chord, Unisoft (methafilcon A) Spherical, Aspherical, Toric and Multifocal Hydrophilic Contact Lens (clear and tinted

powers:	20.00 to -20.00D
Center Thickness:	0.17 mm
Diameter:	14.5 mm
Base Curve:	8.3 mm and 8.6 mm

For the Multifocal Design: Add Powers: Continuous adds to +3.25

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 30 1998

Stephen A. Dunn, Inc.
c/o Mr. Martin S. Knopf
President and CEO
Knopf Associates, Inc.
90 West Main Street
Freehold, NJ 07728

Re: K980818
Trade Name: PolyVue, Silver Chord and Unisoft (methafilcon A) Spherical, Aspherical, Toric and Multifocal Hydrophilic Contact Lenses for Daily Wear (clear and visibility tint)
Regulatory Class: II
Product Code: 86 LPL
Dated: February 27, 1998
Received: March 3, 1998

Dear Mr. Knopf:

We have reviewed your Section 510(k) notification of intent to market the devices referenced above and we have determined the devices are 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 devices, 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 devices are 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 devices 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 devices 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.

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

If you desire specific advice for your devices 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 devices, 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

INDICATIONS STATEMENT

Device Name: PolyVue Silver Chord, Unisoft (methafilcon A) Spherical, Aspherical, Toric and Multifocal Hydrophilic Contact Lenses for Daily Wear

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Eyecare practitioners may prescribe the lens for daily wear in a Frequent Replacement Program. The lenses may be disinfected using heat, chemical or hydrogen peroxide disinfection systems.

(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 _____

Daniel W. C. Brown Ph.D (Optional Format 1-2-96)

(Division Sign-Off)

Division of Ophthalmic Devices

510(k) Number K980818