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: K013220

Applicant information:

Date Prepared:	September 19th, 2000
Name:	**PolyVue Technologies, Inc.**
Address	Seven Hazel Avenue Larkspur, CA 94939
Contact Person:	Mr. Harold E. Johnson President/CEO
Phone number:	(415) 945-9043
USA Consultant:	Med-Vice Consulting, Inc. Mr. Martin Dalsing
Phone number:	(970) 243-5490
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Email address:	mdalsing@FDApproval.com

Device Information:

Device Classification:	Class II
Classification Number:	LPL
Classification Name:	Lenses, Soft Contact, Daily Wear

Trade Name: **HD/HDT, PV/PVT (polymacon) Soft Contact Lens for Daily Wear (clear and tinted, fully cast-molded lens)**

Purpose of 510(k) Submission:

NEW DEVICE ~

PolyVue Technologies, Inc. proposes to market and sell in United States interstate commerce, a fully cast-molded soft contact lens of the (polymacon) soft contact lens material. The device will be made available in four product configurations; 1) the High Definition (HD) aspheric lens, 2) the High Definition Toric (HDT) aspheric toric lens, 3) the PolyVue (PV) multi-aspheric multifocal lens, and 4) the PolyVue Toric (PVT) multi-aspheric toric multifocal lens. Data supporting substantial equivalency to the predicate device, performance, and safety & efficacy of the (polymacon) polymer is authorized through a letter granting PolyVue Technologies, Inc. complete referencing rights to 510(k) K002099 from Bescon Co. Ltd. and is contained in this submission.

Equivalent Devices:

The **HD/HDT, PV/PVT** (polymacon) Soft Contact Lenses are substantially equivalent to the following predicate devices:

Predicate devices:

- "PolyVue" (polymacon) K982110, approval by Optech, Inc.
- "PolyVue Silver Chord, Unisoft (methafilcon A) K980818, approval by Steven A. Dunn, Inc.
- "Hydron Biomedics" (polymacon) P780007, approval by Ocular Sciences, Inc.

Device Description:

The **HD/HDT, PV/PVT** (polymacon) Soft Contact Lenses are hemispherical shells with molded spherical base curves and molded front surfaces.

The nonionic lens material, (polymacon) is a hydrophilic polymer of 2- Hydroxyethyl methacrylate (2-HEMA) and cross-linked with ethylene glycol dimethacrylate (EGDMA), plus an initiator. The co-polymer consists of 62% polymacon and 38% water by weight when immersed in normal buffered saline solution. The lenses are available clear or tinted. Lenses that contain a unique tinting pattern are subsequently processed to incorporate the *'listed'* color additives and contain only the amount of color additive needed to accomplish the intended coloring effect. Lenses are tinted with one or a combination of one or more of the following pigments, *'listed'* color additives.

Phthalocyanine blue (21 CFR § 74.3045), Phthalocyanine green (21 CFR § 73.3124) and Titanium dioxide (21 CFR § 73.3126)

In the hydrated state, the lens conforms to the curvature of the eye covering the cornea and extending slightly beyond the limbus forming a transparent optical surface. The (polymacon) 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.

The hydrophilic characteristics allow aqueous solutions to enter the lens and in its fully hydrated state the lens is approximately 38% water by weight. The physical properties of the lens are:

Refractive Index	1.43 (hydrated)
Light Transmission (clear)	greater than 90%
Light Transmission (tinted)	greater than 90%
Water Content	38 % ± 2%
Oxygen Permeability	8.4 X 10^{-11} (cm^2/sec) (ml O_2/ml x mm Hg @ 35°C), (revised Fatt method).

Intended Use:

The **HD (polymacon) Aspheric** 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 1.50 diopters or less where the astigmatism does not interfere with visual acuity. The lens is available clear or tinted and may be used to enhance or alter the apparent color of the eye.

The **HDT (polymacon) Aspheric Toric** Soft Contact Lenses for daily wear are indicated for the correction of visual acuity in not aphakic persons with non-diseased eyes with myopia or hyperopia and/or possesses refractive astigmatism not exceeding 5.00 diopters. The lens is available clear or tinted and may be used to enhance or alter the apparent color of the eye.

The **PV (polymacon) Multi-Aspheric Multifocal** Soft Contact Lenses for daily wear are indicated for the correction of visual acuity in not aphakic persons with non-diseased eyes with myopia or hyperopia and are presbyopic. The lens may be worn by persons who exhibit refractive astigmatism of 1.50 diopters or less where the astigmatism does not interfere with visual acuity. The lens is available clear or tinted and may be used to enhance or alter the apparent color of the eye.

The **PVT (polymacon) Multi-Aspheric Toric Multifocal** Soft Contact Lenses for daily wear are indicated for the correction of visual acuity in not aphakic persons with non-diseased eyes with myopia or hyperopia, possesses refractive astigmatism not exceeding 5.00 diopters and are presbyopic. The lens is available clear or tinted and may be used to enhance or alter the apparent color of the eye.

Eyecare practitioners may prescribe any of the above lenses for frequent/planned replacement wear, with cleaning disinfection and scheduled replacement. When prescribed for frequent/planned replacement wear, the lens may be disinfected using a chemical disinfecting system.

Pre-Clinical Performance Data:

PolyVue Technologies, Inc. has complete reference and privilege rights to K002099. Pre-clinical performance data addressing the cytotoxicity test, systemic injection test, and ocular eye irritation test can be referenced in the 510(k) # K002099. In addition, data for all relevant manufacturing information, including verification data can be referenced in the 510(k) # K002099.

Concerning compatibility testing, the recommended lens care products (cleaning, rinsing and disinfection) have been approved for use with lenses of the same lens group. Therefore, no additional compatibility testing is included.

With regard to preservative uptake and release studies, since the subject contact lens material (polymacon) is not a new and/or modified lens material, no additional studies need be conducted.

Substantial Equivalence:

The **HD/HDT, PV/PVT** Soft Contact Lens will be manufactured according to specified process controls and a CGMP quality assurance program currently in place and referenced in 510(k) K002099. The final lens packaging and sterilization of the lenses will be carried out in accordance with referenced PMA's & 510(k)'s; K954524, K983021, K973597, K970312, P830012 and P820051.

The established safety profile (pre-clinical toxicology and manufacturing/chemistry data) of the **HD/HDT, PV/PVT** material is equivalent to the predicate devices identified previously. Being similar with respect to indications for use, target population, hydrophilic materials, physical construction and safety & effectiveness to the predicate devices, this meets the requirements per section 510(k) of the act regarding substantial equivalence and *does not raise* different questions of safety and effectiveness than the predicate device identified above.

The following matrix illustrates the equivalencies between the **HD/HDT, PV/PVT** Soft Contact Lens and the substantial equivalent predicate devices.

Substantial Equivalence Matrix

Substantial Equivalency	HD/HDT, PV/PVT 'Subject Device'	Hydron Biomedics 38 'Predicate Device'	PolyVue 'Predicate Device'	PolyVue Silver Chord 'Predicate Device'
Manufacture	**PolyVue Technologies**	**Ocular Sciences, Inc.**	**Optech, Inc.**	**Steven A. Dunn, Inc.**
INDICATION	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 5.00 diopters, and/or are presbyopic.	Soft Contact lenses for daily wear are indicated 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 2.50 diopters.	Soft Contact lenses for daily wear are indicated for the correction of refractive ametropia (myopia and hyperopia), presbyopia and astisgmatism in aphakic and not aphakic persons with non-diseased eyes.	Soft Contact lenses for daily wear are indicated for the correction of refractive ametropia (myopia and hyperopia), and astisgmatism in aphakic and not aphakic persons with non-diseased eyes.
INTENDED USE	Daily Wear, Soft (hydrophilic) Contact Lens	Daily Wear, Soft (hydrophilic) Contact Lens	Daily Wear, Soft (hydrophilic) Contact Lens	Daily Wear, Soft (hydrophilic) Contact Lens
Manufacturing Method	Fully-molded	Fully-molded	Lathe-cut (Semi-Mold)	Lathe-cut (Semi-Mold)
USAN name Material name	polymacon	polymacon	polymacon	methafilcon A
Water Content (%)	38.0%	38.0%	38.0%	55.0%
Toxicity (safety)	Non-Toxic	Non-Toxic	Non-Toxic	Non-Toxic

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 2 0 2001

PolyVue Technologies, Inc.
c/o Martin Dalsing
Medvice Consulting, Inc.
623 Glacier Drive
Grand Junction, CO 81503

Re: K013220
Trade/Device Name: HD/HDT, PV/PVT (polymacon) Soft Contact Lens for Daily Wear (clear and tinted, fully cast-molded lens)
Regulation Number: 21 CFR 886.5925
Regulation Name: Lenses, Soft Contact, Daily Wear
Regulatory Class: Class II
Product Code: LPL
Dated: September 19, 2001
Received: September 26, 2001

Dear Mr. Dalsing:

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.

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 and additionally 21 CFR Part 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" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained 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

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

K013220

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INDICATIONS FOR USE STATEMENT

Device Name: **HD/HDT, PV/PVT (polymacon) Soft Contact Lens for Daily Wear (clear and tinted, fully cast-molded lens)**

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The **PVT (polymacon) Multi-Aspheric Toric Multifocal** Soft Contact Lenses for daily wear are indicated for the correction of visual acuity in not aphakic persons with non-diseased eyes with myopia or hyperopia, possesses refractive astigmatism not exceeding 5.00 diopters and are presbyopic. The lens is available clear or tinted and may be used to enhance or alter the apparent color of the eye.

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(PLEASE DO OT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Daniel W. C. Brown, Ph.D.

(Division Sign-Off)
Division of Ophthalmic Devices
510(k) Number K013220

Prescription Use X
(Per 21 CFR 801.109)

or

Over-The-Counter Use __

(Optional Format 1-2-96)