4/21/99

K 9 84436

APPENDIX H
510(k) Summary

Submitter. Company Name: **Paragon Vision Sciences**
Address: **945 East Impala Ave.**
Phone: **602-892-7602**
Fax: **602-892-3226**
Registration: Owner Operator # **9024618**

Manufacturer:
Company Name: **Paragon Vision Sciences**
Address: **945 East Impala Ave. Mesa AZ 85204**
Phone: **602-892-7602**
Fax: **602-892-3226**:
Registration. **Site Registration #2020433**

Official Correspondent: **William E. Meyers, Ph.D.**
% Paragon Vision Sciences
Address: **945 East Impala Ave. Mesa AZ 85204**
Phone: **602-507-7606**
Fax: **602-892-3226**
Reason for 510(k) Submission: **Material change**

Date of submission **12/10/98**

Device Identification:
Trade Name: **PVS BASICS ™**
Common Name: **contact lens**
Classification Name: **rigid gas permeable contact lens for daily wear**
Reference: **21 CFR 886.5916;rigid gas permeable contact lens, Class II- daily wear**

Indications For Use:

The **PVS BASICS ™ (paflufocon E)** rigid gas permeable contact lenses are indicated for daily wear as recommended by the eye care practitioner. The **PVS BASICS ™ (paflufocon E)** rigid gas permeable spherical, aspheric and bifocal contact lenses are indicated for the correction of visual acuity in not-aphakic persons with non-diseased eyes who are nearsighted (myopic), farsighted (hyperopic) and who may exhibit corneal astigmatism up to 4.00 diopters or less that does not interfere with visual acuity. **PVS BASICS ™ (paflufocon E)** toric contact lenses are indicated to correct astigmatism of up to 6.00 diopters. **PVS BASICS ™** Bifocal lenses are indicated for presbyopic persons (far or near sighted) including astigmatic corrections up to +4.00 D requiring add power of up to + 4.00 D.

The lenses have the following dimensions and characteristics:

Parameters	**PVS BASICS ™**
Material	Paflufocon E
Indication	Daily wear
Water content	< 1%
Dk (35)°	67*
Light transmittance Violet****	**92%**
Wetting Angle***	16
Hardness	81.7
refractive index	1.454
Specific gravity	1.10
color	violet

*Oxygen Permeability 67 $x10^{-11}$Dk** at 35'C
**(cm2/sec)(mL 02/mL x mm Hg) Method of Irving Fatt, Ph.D.
*** after soaking in conditioning solution
**** +12 D, 7mm OZ, 7.8 BC, .45mm CT, harmonic mean thickness over 7mm = 0.329 mm.

Lens Parameters:

Chord Diameter	7.0 to 10.5 mm
Center Thickness	0.05 to 0.70 mm
Base Curve	6.50 to 9.00 mm
Powers	20.00 to +12.00 Diopters

Bifocal Add Powers....+O.25to +4.00 Diopters
Concentric Bifocal
Add Diameter.....2.0 to 4.0 mm
Monocentric Bifocal
Add Diameter.....4.0 to 9.0 mm
Monocentric Bifocal
Prism..... 1.0 to 2.5 Diopters

The **PVS BASICS ™ (paflufocon E)** rigid gas permeable contact lenses are available in violet color. The violet tinted lenses contain D & C Violet # 2 and D & C Red #17.

The **PVS BASICS ™ paflufocon E)** Dk 65 contact lens is substantially equivalent to the FluoroPerm 92® (paflufocon A) Dk 92 Rigid Gas Permeable Contact Lens marketed by Paragon Vision Sciences which is presently approved for daily wear under PMA (P820063). The physical, optical and chemical properties of the **PVS BASICS ™ (paflufocon E)** contact lens are substantially equivalent to the FluoroPerm 92 (paflufocon A).

In addition to the physicochemical comparison, toxicity and human clinical studies were conducted.

The test article, PVS Basics (AKA paflufocon E), Batch 234880-6, was extracted in 0.9% sodium chloride USP solution (SC) and cottonseed oil, NF (CSO). These extracts were evaluated for ocular irritation base on the International Organization for Standardization 10993: Biological Evaluation of Medical Devices, Part 10: Tests for Irritation and Sensitization.

A 0.2 ml dose of the appropriate test article extract was instilled in the right eye of three test rabbits. Similarly, the corresponding reagent control was instilled into the left eye of each rabbit to serve as the control condition. Ocular reactions were evaluated at 1, 24, 48, and 72 hours after the single exposure.

Under the conditions of this study, there was no evidence of irritation in the test eye or control eye of any rabbit.

The SC and CSO test article extracts would not be considered irritants to the ocular tissue of the rabbit.

An in vitro biocompatibility test, based on the International Organization for Standardization (ISO 10993-5) guidelines, was conducted on the test article, PVS Basics (AKA paflufocon E), Lot HS401710-8, in order to determine the potential for in vitro cytotoxicity. A single lens was placed on triplicate agarose surfaces directly overlaying confluent monolayers of L-929 mouse fibroblast cells. Similarly, triplicate negative and positive control wells were prepared. After incubating at 37°C in 5% CO_2 for 24-26 hours, the cell cultures were examined macroscopically for cell decolorization around the test article and controls to determine the zone of cell lysis (if any). The cultures were then examined microscopically (100X) to verify any decolorized zones and to determine cell morphology in proximity to and beneath the test article.

The negative controls and the positive controls performed as anticipated. Under the conditions of this study, the test article showed no evidence of causing cell lysis or toxicity. The test article was not cytotoxic and passed this ISO study.

A guinea pig maximization test of PVS Basics (AKA paflufocon E), Batch 234880-6, was conducted to evaluate the potential for delayed dermal contact sensitization. This study was conducted based on the requirements of the International Organization for Standardization 10993: Biological Evaluation of Medical Devices, Part 10: Tests for Irritation and Sensitization.

The test article was extracted in 0.9% sodium chloride USP (SC) and cottonseed oil, NF (CSO). Each extract was intradermally injected and occlusively patched to ten test guinea pigs (per extract) in an attempt to induce sensitization. The vehicle was similarly injected and occlusively patched to five control guinea pigs (per vehicle). Following a recovery period, the test and control animals received a challenge patch of the appropriate test article extract and the reagent control. All sites were scored at 24, 48 and 72 hours after patch removal.

Under the conditions of this study, the SC and CSO test article extracts showed no evidence of causing delayed dermal contact sensitization in the guinea pig.

A clinical evaluation of the safety and effectiveness of the paflufocon E [PVS Basic™] polymer lens was performed. This randomized double-masked controlled clinical trial evaluated the clinical performance of lenses produced using the new paflufocon E material in comparison to control lenses made with FDA approved predicate material, paflufocon A (FluoroPerm 92™).

Decision criteria were established for the purpose of testing the equivalence of the materials these variables were: Visual Acuity, Comfort, Lens-Eye Relationship, Movement, Slit lamp Findings, Functional Wetting.

This clinical trial established Paflufocon E as safe and effective when compared to the currently marketed predicate control material, Paflufocon A (FluoroPerm 92™). The tables below summarize the results of the study.

EYES ENROLLED IN THE STUDY
AND DISTRIBUTION AND STATUS

Status		Number of Eyes	
		Paflufocon A TOTALS	PVS Basics TOTALS
Enrolled Dispensed			
Completed		22	68
Active			
	Dispensing	22	70
	First Follow Up	22	68
	Final Visit	22	68
Total Active		22	68
Discontinued		0	2
Incomplete		0	0
Total Dispensed		22	70
Enrolled Not Dispensed		0	0
Total Enrolled		22	70

SUMMARY OF FINDINGS RELATED TO SAFETY

	Paflufocon A TOTALS	PVS Basics TOTALS
NUMBER OF EYES	22	68
DISCONTINUED EYES	0	2
AVERAGE WEARING TIME	~~0~~ 14.09	~~0~~ 13.58 TMC.
ALL ADVERSE REACTIONS	0	0
ALL CORNEAL ULCERS	0	0
ALL IRITIS	0	0
STAINING REPORTS > GRADE 2	0	0
EDEMA REPORTS >GRADE 2	0	0
INJECTION REPORTS >GRADE 2	0	0
NEOVASC. REPORTS >GRADE 2	0	0
VISITS	44	136
MISSED VISITS	0	0

SUMMARY OF SYMPTOMS PROBLEMS AND COMPLAINTS

Completed Control Eyes

	Initial Dispensing Visit		Intermediate Visits			
			1		2	
Total Eyes at Visit	22		22		22	
	Number	Percent	Number	Percent	Number	Percent
None	19	86.4	16	72.7	14	63.6
Discomfort	3	13.6	4	18.2	6	27.3
Excess Tearing *	0	0	0	0	0	0
Photophobia	0	0	0	0	0	0
Halos	0	0	0	0	0	0
Itching/Burning	0	0	1	4.5	4	18.2
Spectacle Blur*	0	0	0	0	0	0
Variable Vision	0	0	0	0	4	18.2
Blurred Vision	2	9.1	3	13.6	8	36.4
Lens Needs Cleaning	2	9.1	3	13.6	2	9.1
Other						
Dryness	2	9.1	3	13.6	6	27.3
Total Positive Reports	9		14		24	

Completed Trial Eyes

	Initial Dispensing Visit		Intermediate Visits			
			1		2	
Total Eyes at Visit	70		68		68	
	Number	Percent	Number	Percent	Number	Percent
None	55	78.6	52	76.5	45	66.2
Discomfort	6	8.6	4	5.9	8	11.8
Excess Tearing	0	0	0	0	0	0
Photophobia	0	0	0	0	0	0
Halos	2	2.9	0	0	2	2.9
Itching/Burning	1	1.4	2	2.9	2	2.9
Spectacle Blur	0	0	0	0	0	0
Variable Vision	0	0	6	8.8	5	7.4
Blurred Vision	4	5.7	4	5.9	2	2.9
Lens Needs Cleaning	0	0	6	8.8	4	5.9
Other						
Dryness	5	7.1	5	7.4	6	8.8
Total Positive Reports	18		27		29	

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 21 1999

William E. Meyers, Ph.D.
Vice President, Science & Technology
PARAGON VISION SCIENCES
947 East Impala
Mesa, AZ 85204

Re: K984436
Trade Name: PVS BASICS ™ (paflufocon E) Rigid Gas Permeable Contact Lenses
For Daily Wear (Spherical,
Aspheric, Toric and Bifocal) Clear and Violet Tinted
(with D&C Violet # 2 and D & C Red # 17)
Regulatory Class: II
Product Code: 86 HQD
Dated: March 2, 1999
Received: March 3, 1999

Dear Dr. Meyers:

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

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

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

Enclosure

Indications Statement

510(k) Number (if known):

Device Name: **PVS BASICS ™ (paflufocon E)**Contact Lens

Indications For Use:

The **PVS BASICS ™ (paflufocon E)** rigid gas permeable contact lenses are indicated for daily wear as recommended by the eye care practitioner. The **PVS BASICS ™ (paflufocon E)** rigid gas permeable spherical, aspheric and bifocal contact lenses are indicated for the correction of visual acuity in not-aphakic persons with non-diseased eyes who are nearsighted (myopic), farsighted (hyperopic) and who may exhibit corneal astigmatism up to 4.00 diopters or less that does not interfere with visual acuity. **PVS BASICS ™ (paflufocon E)** toric contact lenses are indicated to correct astigmatism of up to 6.00 diopters. **PVS BASICS ™** Bifocal lenses are indicated for presbyopic persons (far or near sighted) including astigmatic corrections up to +4.00 D requiring add power of up to + 4.00 D.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The Counter Use _____

(Optional **Format 1-2-96**)

(Division Sign-Off)
Division of Ophthalmic Devices
510(k) Number K 984436