APR 2 5 2002

APPENDIX H

K013310

510(k) Summary

Submitter

Company Name:	**Paragon Vision Sciences**
Address:	**945 East Impala Ave., Mesa, AZ 85204**
Phone:	**480-892-7602**
Fax:	**480-892-3226**
Registration:	Owner Operator # **9024618**

Manufacturer Information

Company Name:	**Paragon Vision Sciences**
Address:	**945 East Impala Ave., Mesa, AZ 85204**
Phone:	**480-892-7602**
Fax:	**480-892-3226**
Registration:	Site Registration **#2020433**

Official Correspondent

Name:	**William E. Meyers, Ph.D.**
Address:	**% Paragon Vision Sciences**
Address:	**945 East Impala Ave., Mesa AZ 85204**
Phone:	**480-507-7606**
Fax:	**480-892-3226**

Reason for 510(k) Submission:

Material change

Date of Submission:

10/02/01

Device Identification:

Trade Name:	**PVS Basic™ 2 and Epic® 2**
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 contact lens**

Indications For Use:

The PVS Basic™ 2 (migafocon A) and Epic® 2 (migafocon A) rigid gas permeable contact lenses are indicated for daily wear as recommended by the eye care practitioner. The PVS Basic™ 2 (migafocon A) and Epic® 2 (migafocon A) 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 that does not interfere with visual acuity. PVS Basic™ 2 (migafocon A) and Epic® 2 (migafocon A) toric contact lenses are indicated to correct astigmatism of up to 6.00 diopters. PVS Basic™ 2 (migafocon A) and Epic® 2 (migafocon A) bifocal lenses are indicated for presbyopic persons (farsighted or nearsighted), 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.

Characteristics	PVS Basic™ 2 and Epic® 2
Material	migafocon A
Indication	Daily Wear
Water Content	< 1%
Oxygen Permeability*	74 x 10^{-11} Dk at 35° C
Oxygen Permeability**	52 x 10^{-11} Dk at 35° C
Luminous Transmittance (blue)***	87%
Wetting Angle (receding angle)****	16
Hardness (Shore D)	82.6
Refractive Index*****	1.454 (nD at 25° C)
Specific Gravity	1.10
Color	Blue

* (cm^2/sec) / (mL x mm Hg) Revised Method of I. Fatt
** (cm^2/sec) / (mL x mm Hg) ISO/ANSI Method, ISO 9913-1
*** ANSI Z80.20 – 1998 and ISO 8699: 1994
**** After soaking in conditioning solution
***** ISO 9914: 1995

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
Power	- 20.00 to +12.00 Diopters
Bifocal Add Power	+ 0.25 to +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	0 to 2.5 Diopters

The PVS Basic™ 2 (migafocon A) and Epic® 2 (migafocon A) rigid gas permeable contact lenses are available in blue. The blue tinted lenses contain D&C Green # 6.

Under the conditions of the cytotoxicity study using the ISO Agarose Overlay Method, the test article showed no evidence of causing cell lysis or toxicity. The test article met the requirements of the USP since the grade was less than a grade 2 (mild reactivity). The negative control and the positive control performed as anticipated.

Under the conditions of the ISO acute systemic toxicity study in the mouse, there was no mortality or evidence of systemic toxicity from the extracts. Each test article extract met the test requirements.

Under the conditions of the ISO ocular irritation study in the rabbit, the SC and CSO test article extracts would not be considered irritants to the ocular tissue of the rabbit.

The PVS Basic™ 2 (migafocon A) and Epic® 2 (migafocon A) Dk 74 contact lenses are substantially equivalent to the PVS Basics™ Dk 67 rigid gas permeable contact lens marketed by Paragon Vision Sciences which is presently approved for daily wear 510(k), K984436. The physical, optical and chemical properties of PVS Basic™ 2 (migafocon A) and Epic® 2 (migafocon A) contact lenses are substantially equivalent to PVS Basics™ (paflufocon E) contact lenses. See table of next page.

Similarities and Differences

Physical Characteristics

Parameters	PVS Basic™ 2 & Epic® 2	PVS Basics™
Material	migafocon A	paflufocon E
Indication	Daily Wear	Daily Wear
Water Content/Absorption [1]	< 1%	< 1%
Oxygen Permeability, Revised Fatt Method [2]	74×10^{-11}	67×10^{-11}
Oxygen Permeability, ISO/ANSI Method [3]	52×10^{-11}	35×10^{-11}
Luminous Transmittance @ +12 D, 7mm OZ, 7.8 BC, .45mm CT, harmonic mean thickness over 7mm = 0.329 mm [4]	87%	87%
Wetting Angle (receding angle)[5]	16	16
Hardness (Shore D)	82.6	81.7
Refractive Index, nD @ 25°C [6]	1.454	1.454
Specific Gravity	1.10	1.10
Modulus (kgf/cm^2) [7]	16334	14962
Flexural Strength Stress @ Break (kgf/cm^2) [7]	460	436
Flexural Strain [7]	3.6%	3.6%
Toughness (gf – mm) [7]	366	354
Color	Blue	Blue
UV Absorber	None	None

[1] ANSI Z80.20 – 1998, Method 8.22
[2] (cm^2/sec) (mL x mm Hg) Revised Method of I. Fatt, [Dk (at 35°C)]
[3] (cm^2/sec) (mL x mm Hg) ISO/ANSI Method, ISO 9913-1, [Dk (at 35°C)]
[4] ANSI Z80.20 – 1998 and ISO 8599: 1994
[5] After soaking in conditioning solution
[6] ISO 9914:1995
[7] ANSI Z80.20 – 1998; ASTM D790M - 92

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 2 5 2002

Paragon Vision Sciences
c/o William E. Meyers, Ph.D.
947 East Impala
Mesa, AZ 85204

Re: K013310
Trade/Device Name: PVS Basic™ 2 and Epic® 2
Regulation Number: 21 CFR 886.5916
Regulation Name: Rigid Gas Permeable Contact Lens
Regulatory Class: Class II
Product Code: HQD
Dated: October 2, 2001
Received: October 4, 2001

Dear Mr. Meyers:

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 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

Indications Statement

510(k) Number (if known): **K013310**

Device Name: PVS Basic™ 2 (migafocon A) and Epic® 2 (migafocon A) Contact Lenses

Indications For Use:

The PVS Basic™ 2 (migafocon A) and Epic® 2 (migafocon A) rigid gas permeable contact lenses are indicated for daily wear as recommended by the eye care practitioner. The PVS Basic™ 2 (migafocon A) and Epic® 2 (migafocon A) 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 that does not interfere with visual acuity. PVS Basic™ 2 (migafocon A) and Epic® 2 (migafocon A) toric contact lenses are indicated to correct astigmatism of up to 6.00 diopters. PVS Basic™ 2 (migafocon A) and Epic® 2 (migafocon A) bifocal lenses are indicated for presbyopic persons (farsighted or nearsighted), 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 x OR Over-The Counter Use _____

Daniel W. G Brown Ph.D.

(Optional Format 1-2-96)

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

510(k) Number K013310