

MAY 22 2000

K 993586

510(k) Summary

Submitter. Company Name: **Paragon Vision Sciences**
Address: **947 East Impala Ave. Mesa AZ 85204**
Phone: **480-892-7602**
Fax: **480-892-3226**
Registration: **Owner Operator # 9024618**

Manufacturer:
Company Name: **Paragon Vision Sciences**
Address: **947 East Impala Ave. Mesa AZ 85204**
Phone: **480-892-7602**
Fax: **480-892-3226**
Registration. **Site Registration #2020433**

Official Correspondent: **William E. Meyers, Ph.D.**
% **Paragon Vision Sciences**
Address: **947 East Impala Ave. Mesa AZ 85204**
Phone: **480-507-7606**
Fax: **480-892-3226**

Reason for 510(k) Submission: **Material change**

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

Device Identification:
Trade Name: **SportSight GP™**
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 SportSight™ GP (paflufocon C) rigid gas permeable contact lenses are indicated for daily wear as recommended by the eye care practitioner. The SportSight™ GP (paflufocon C) 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. SportSight™ GP (paflufocon C) toric contact lenses are indicated to correct astigmatism of up to 6.00 diopters. SportSight™ GP (paflufocon C) 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. SportSight™ GP (paflufocon C) contact lenses are indicated for the attenuation of bright light and the reduction of glare. SportSight™ GP (paflufocon C) contact lenses help protect against transmission of harmful UV radiation to the cornea and into the eye

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The lenses have the following dimensions:

SPORTSIGHT GP (paflucocon C)

Refractive Index	1.466(Nd at 25°C)
Luminous Transmittance (driving allowed)	8% - 26%**
Luminous Transmittance (driving prohibited)	1% - 8%**
Wetting Angle (Receding Angle)	12.81
Specific Gravity	1.14
Hardness (Shore D)	84
Water Content	<1%

Oxygen Permeability 30 x 1 0-1 1 Dk* at 35°C *(cm²/sec)(mL O₂/mL x mm Hg) Revised method of Irving Fatt, Ph.D.
**harmonic mean transmission over 4mm

Lens Parameters:

Chord Diameter	7.0 to 14.5 mm
Center Thickness (driving allowed)	0.09 - 0.275 mm
Center Thickness (driving prohibited)	0.275 - 0.475 mm
Base Curve	6.50 to 9.00 mm
Powers	-20.00 to +12.00 Diopters
Bifocal Add Powers	+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	1.0 to 2.5 Diopters

The SportSight GP (paflucocon C) intensely tinted, rigid gas permeable contact lenses are available in SportSight Gray. The Gray tinted lens contains D&C Red # 17, D & C Green No. 6, and Perox Yellow No. 9.

The **SPORTSIGHT™ GP paflucocon C** Dk 30 contact lens is substantially equivalent to the FluoroPerm 30®(paflucocon C) Dk 30 Rigid Gas Permeable Contact Lens marketed by Paragon Vision Sciences which is presently approved for daily wear under PMA (P820063). With the exception of light Transmission, the physical, optical and chemical properties of the SportSight™ GP (paflucocon C) contact lens are substantially equivalent to the FluoroPerm 30 (paflucocon C).

The SportSight™GP product is intended to provide vision correction, as does any RGP contact lens and further to provide the attenuation of bright light and glare. In addition, the lens is specifically designed to provide a minimum of 99 % reduction of UVA, and UVB entering the eye, and to reduce the transmission of blue light (< 500 nm) into the eye. The lens will provide these functions without compromising recognition of traffic signals unless labeled to the contrary.

The SportSight™GP product

- Reduces transmission of UVA and UVB by greater than 99%.
- Reduces overall light transmission to the retina. The minimum overall light attenuation is 74 % and is 82 % in the recommended design.
- Reduces blue light transmission to the retina. The minimum blue light attenuation is 77 % and is 85% in the recommended design.
- Meet the ANSI Z80.3-1996 Standard for Nonprescription Sunglasses and Fashion Eyewear (table 4) requirements for minimal transmission of red, green and yellow light to assure traffic light recognition unless labeled to the contrary.

It is not recommended that practitioners prescribe lenses that do not meet the ANSI Z80.3-1996 Standard for Nonprescription Sunglasses and Fashion. In the event that such devices are dispensed it is required that they be labeled "CAUTION, NOT FOR USE WHEN DRIVING".

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The light transmittance properties for the SportSight material are summarized in the following table. The description of these measurements is found in the ANSI Z80.3-1996 Standard for Nonprescription Sunglasses and Fashion Eyewear.

Power [Diopter]	Center Thick -ness Limits	Luminous Transmittance (%)	UV Mean Transmittance (%)		Solar Blue Transmittance (%)	Traffic Signal Transmittance (%)			Chromaticity Coordinates					
			UVB (290-315 nm)	UVA (315-380 nm)		380-500 nm	Red	Yellow	Green	Yellow Signal		Green Signal		Average Daylight D65
			x	y	x	y	x	y						
-20 to +2	Lower	26	0.2	0.2	23	25	21	21	0.58	0.42	0.23	0.41	0.35	0.35
	Recom	18	0.0	0.0	15	16	13	13	0.58	0.42	0.24	0.41	0.36	0.36
	Upper	8	0.0	0.0	6	8	6	6	0.58	0.42	0.26	0.42	0.38	0.37
	Special*	1	0.0	0.0	0.0	REQUIRES WARNING UNSAFE FOR DRIVING AT ANY TIME								
+3	Lower	25	0.2	0.2	22	24	21	21	0.58	0.42	0.23	0.41	0.35	0.35
	Recom	18	0.0	0.0	15		13	13	0.58	0.42	0.24	0.41	0.36	0.36
	Upper	8	0.0	0.0	6	8	6	6	0.58	0.42	0.26	0.42	0.38	0.37
	Special*	1	0.0	0.0	0.0	REQUIRES WARNING UNSAFE FOR DRIVING AT ANY TIME								
+4	Lower	22	0.1	0.1	19	21	18	18	0.58	0.42	0.24	0.41	0.36	0.36
	Recom	18	0.0	0.0	15	16	13	13	0.58	0.42	0.24	0.41	0.36	0.36
	Upper	8	0.0	0.0	6	8	6	6	0.58	0.42	0.26	0.42	0.38	0.37
	Special*	1	0.0	0.0	0.0	REQUIRES WARNING UNSAFE FOR DRIVING AT ANY TIME								
+5	Lower	20	0.1	0.1	17	19	15	15	0.58	0.42	0.24	0.41	0.36	0.36
	Recom	18	0.0	0.0	15	16	13	13	0.58	0.42	0.24	0.41	0.36	0.36
	Upper	8	0.0	0.0	6	8	6	6	0.58	0.42	0.26	0.42	0.38	0.37
	Special*	1	0.0	0.0	0.0	REQUIRES WARNING UNSAFE FOR DRIVING AT ANY TIME								
+6	Lower	17	0.0	0.0	14	16	13	13	0.58	0.42	0.24	0.41	0.36	0.36
	Recom	18	0.0	0.0	15	16	13	13	0.58	0.42	0.24	0.41	0.36	0.36
	Upper	8	0.0	0.0	6	8	6	6	0.58	0.42	0.26	0.42	0.38	0.37
	Special*	1	0.0	0.0	0.0	REQUIRES WARNING UNSAFE FOR DRIVING AT ANY TIME								
+7	Lower	14	0.0	0.0	12	14	11	11	0.58	0.42	0.24	0.42	0.37	0.36
	Recom	14	0.0	0.0	12	14	11	11	0.58	0.42	0.24	0.42	0.37	0.36
	Upper	8	0.0	0.0	6	8	6	6	0.58	0.42	0.26	0.42	0.38	0.37
	Special*	1	0.0	0.0	0.0	REQUIRES WARNING UNSAFE FOR DRIVING AT ANY TIME								
+8	Lower	13	0.0	0.0	10	12	9	9	0.58	0.42	0.25	0.42	0.37	0.37
	Recom	13	0.0	0.0	10	12	9	9	0.58	0.42	0.25	0.42	0.37	0.37
	Upper	8	0.0	0.0	6	8	6	6	0.58	0.42	0.26	0.42	0.38	0.37
	Special*	1	0.0	0.0	0.0	REQUIRES WARNING UNSAFE FOR DRIVING AT ANY TIME								
+9	Lower	11	0.0	0.0	9	10	8	8	0.58	0.42	0.25	0.42	0.38	0.37
	Recom	11	0.0	0.0	9	10	8	8	0.58	0.42	0.25	0.42	0.38	0.37
	Upper	8	0.0	0.0	6	8	6	6	0.58	0.42	0.26	0.42	0.38	0.37
	Special*	1	0.0	0.0	0.0	REQUIRES WARNING UNSAFE FOR DRIVING AT ANY TIME								
+10	Lower	10	0.0	0.0	8	9	7	7	0.58	0.42	0.25	0.42	0.38	0.37
	Recom	10	0.0	0.0	8	9	7	7	0.58	0.42	0.25	0.42	0.38	0.37
	Upper	8	0.0	0.0	6	8	6	6	0.58	0.42	0.26	0.42	0.38	0.37
	Special*	1	0.0	0.0	0.0	REQUIRES WARNING UNSAFE FOR DRIVING AT ANY TIME								
+11	Lower	9	0.0	0.0	7	9	6	6	0.58	0.42	0.25	0.42	0.38	0.37
	Recom	9	0.0	0.0	7	9	6	6	0.58	0.42	0.25	0.42	0.38	0.37
	Upper	8	0.0	0.0	6	8	6	6	0.58	0.42	0.26	0.42	0.38	0.37
	Special*	1	0.0	0.0	0.0	REQUIRES WARNING UNSAFE FOR DRIVING AT ANY TIME								
+12	Lower	8	0.0	0.0	6	8	6	6	0.58	0.42	0.26	0.42	0.38	0.37
	Recom	8	0.0	0.0	6	8	6	6	0.58	0.42	0.26	0.42	0.38	0.37
	Upper	8	0.0	0.0	6	8	6	6	0.58	0.42	0.26	0.42	0.38	0.37
	Special*	1	0.0	0.0	0.0	REQUIRES WARNING UNSAFE FOR DRIVING AT ANY TIME								

*Special prescription lenses with thickness beyond safe driving limit (transmission @ 0.475 mm CT)

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In addition to physicochemical comparison, toxicity studies and biocompatibility studies were conducted. **SportSight™ GP** is composed of the same monomers used in the family of paflucocon products (specifically equivalent to the FluoroPerm 30, paflucocon C formulation). This formulation has been marketed for 10 years by Paragon Vision Sciences. No new components have been added which are not presently in the marketed formulations. Preliminary analysis of batches of each of the colors have not shown the presence of any new residues not previously observed. Paragon Vision Sciences performed a complete battery of toxicology and biocompatibility testing of an extreme case formulation. A batch of polymer having a maximized amount of all three tints used in **SportSight™ GP** was tested for Cytotoxicity, Ocular Irritation, Systemic Toxicity, and Sensitization. All tests showed no signs of toxicity or incompatibility. Similarly, final validation batches for each of the products have been tested for Cytotoxicity and Ocular Irritation and Systemic Toxicity.



MAY 22 2000

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

William E. Meyers, Ph.D.
Vice President, Science & Technology
Paragon Vision Sciences
947 East Impala Ave.
Mesa, Az 85204

Re: K993586

Trade Name: SportSight™ GP (paflucocon C) Intensely Tinted Rigid Gas Permeable Contact Lenses for Daily wear (gray)

Regulatory Class: II
Product Code: 86 HQD
Dated: April 13, 2000
Received: April 17, 2000

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.

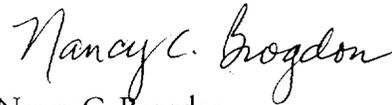
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially 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 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.

Page 2 - William E. Meyers, Ph.D.

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) 594-6413. 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 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/dsma/dsmamain.html>".

Sincerely yours,



Nancy C. Brogdon
Acting 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 (unknown): K 993586

Device Name: SportSight™ GP (paflucocon C) Contact Lens

Indications For Use:

The SportSight GP (paflucocon C) rigid gas permeable contact lenses are indicated for daily wear as recommended by the eye care practitioner. The SportSight GP (paflucocon C) 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. SportSight GP (paflucocon C) toric contact lenses are indicated to correct astigmatism of up to 6.00 diopters. SportSight GP 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. SportSight GP (paflucocon C) contact lenses are indicated for the attenuation of bright light and the reduction of glare. SportSight™ GP (paflucocon C) contact lenses help protect against transmission of harmful UV radiation to the cornea and into the eye.

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 _____

Mig - Clines Shur

(Division Sign-Off)
Division of Ophthalmic Devices

(Optional Format 1-2-96)

510(k) Number K 993586

JS