

3/31/99

**Metro Optics**  
510(k) Premarket Notification

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**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:           K990264          

**Applicant information:**

Date Prepared: January 25th, 1999

Name: Metro Optics, Inc.  
Address: 15802 Vision Drive  
Pflugerville, TX 78660  
P.O. Box 14847  
Austin, Texas 78761

Contact Person: Mr. Steve Webb  
Vice President

Phone Number: (512) 251-2382  
Fax: (512) 251-6554

Official Correspondent: Med-Vice Consulting, Inc.  
Regulatory Consultant: Mr. Martin Dalsing  
623 Glacier Drive  
Grand Junction, CO 81503

Phone Number: (970) 243-5490  
Fax Number: (970) 243 -5501

**Device Information:**

Regulatory Classification: Class II

Product Code: HQD

Trade Name: **ComfortKone™ Keratoconus Aspheric (paflufocon C)  
Rigid Gas Permeable (RGP) Daily Wear Contact Lens  
(Clear and Tinted, Lathe-cut from Lens Blank)**

Classification Name: Lenses, Contact (other material), Daily Wear

# Metro Optics

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### Equivalent Devices:

The ComfortKone™ Keratoconus Aspheric (paflucocon C) Rigid Gas Permeable (RGP) Daily Wear Contact Lens is substantially equivalent to the predicate device identified below in terms of intended use and design.

### Predicate device:

Rose K Lens  
510(k) # K945955  
Manufactured under license by: Lens Dynamics, Inc.  
510(k) Author: Rose K International Limited

### Device Description:

The ComfortKone™ Keratoconus Aspheric Contact Lens is fabricated from the hydrophobic contact lens material (paflucocon C). The material is a thermoset copolymer derived from fluorosilicone acrylate monomer. When placed on the human cornea, the ComfortKone™ Keratoconus Aspheric rigid gas permeable contact lenses act as a refracting medium to focus light rays upon the retina.

The ComfortKone™ is a aspheric contact lens. It is designed to provide optimum comfort and visual acuity to the keratoconus patient. The ComfortKone™ lens design begins with a spherical 4.0 mm optic zone that fits the peak of the cone and provides for good visual acuity. The lens then flattens into the aspheric curve, which is considered the fitting curve of the lens. The aspheric curve will vary in rate of change depending on how far the keratoconus has advanced and creates optimal corneal alignment. The design finishes with two junctionless peripheral aspheric curves to maintain alignment.

The physical properties of the lens are:

<b>Refractive Index</b>	1.475 (Nd at 25°C)
<b>Light Transmission (clear)</b>	93 %
<b>Light Transmission (blue)</b>	91 %
<b>Light Transmission (gray)</b>	91 %
<b>Light Transmission (green)</b>	92 %
<b>Wetting Angle (receding angle)</b>	12.8°
<b>Specific Gravity</b>	1.14
<b>Hardness (shore D)</b>	84
<b>Water Content</b>	< 1%
<b>Color Pigment Names</b>	D & C Green No. 6, Perox Yellow No. 9, D & C Violet No. 2 21 CFR § 74.3206, § 73.3122, § 74.3602
<b>Oxygen Permeability</b>	$30 \times 10^{-11}$ (cm <sup>2</sup> /sec) (ml O <sub>2</sub> /ml x mm Hg @ 35°C), revised Irving Fatt method.

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**Intended Use:**

The **ComfortKone™ Keratoconus Aspheric (paflucocon C) Rigid Gas Permeable (RGP) Daily Wear Contact Lens (Clear and Tinted, Lathe-cut from Lens Blank)** is indicated for daily wear for persons requiring Keratoconus management with otherwise non-diseased eyes. The lens may be prescribed for the correction of refractive ametropia (myopia, hyperopia and astigmatism) in aphakic and not-aphakic persons. The lens may be disinfected with a chemical disinfection system.

**Substantial Equivalence:**

The new device will be manufactured according to specified process controls and a Quality Management System certified to CGMP guidelines. The new device will undergo manufacturing, packaging and other process procedures similar to RGP devices currently marketed and distributed by Metro Optics, Inc. in the USA. The established safety profile (pre-clinical toxicology and manufacturing/chemistry data) of the device is equivalent to the Rose K Lens (RGP), 510(k) #K945955. Being similar with respect to indications for use, materials, physical construction and safety & effectiveness to the predicate device, 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 that the production method, lens function and material of the ComfortKone™ Keratoconus Aspheric (paflucocon C) Rigid Gas Permeable (RGP) Daily Wear Contact Lens are substantially equivalent to the predicate device. In addition, the water content, polymer, Dk value, refractive index, specific gravity, wetting angle and light transmission are as well substantially equivalent to the predicate device.

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**SUMMARY OF SAFETY AND EFFECTIVENESS**  
**Substantial Equivalence Matrix**

	<b>Characteristic</b>	<b>ComfortKone Keratoconus Aspheric</b>	<b><i>Predicate Device:</i> ROSE K LENS Keratoconus Aspheric</b>
1.)	<b>PRODUCTION METHOD</b>	Lathe-Cut	Lathe-Cut
2.)	<b>LENS FUNCTION</b>	Keratoconus management. Refractive medium that focuses light rays from near and distant objects on the retina, while compensating for refractive error, including (astigmatism)	Keratoconus management. Refractive medium that focuses light rays from near and distant objects on the retina, while compensating for refractive error, including (astigmatism)
3.)	<b>RGP MATERIAL</b>	Rigid Gas Permeable (RGP) Fluorperm 30	Rigid Gas Permeable (RGP) Boston ES
a.	Water Content	< 1%	< 1%
b.	Polymer	(paflucocon C)	(enflucocon A)
c.	Oxygen Permeability	30	31
d.	Refractive Index	1.475	1.443
e.	Specific Gravity	1.14	1.22
f.	Wetting Angle	12.8 deg.	52.0 deg.
g.	Light Transmission (clear lens)	> 93 %	> 84 %



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

MAR 31 1999

Mr. Martin Dalsing  
Official FDA Correspondent for Metro Optics, Inc.  
Medvice Consulting, Inc.  
623 Glacier Drive  
Grand Junction, CO 81503

Re: K990264

Trade Name: ComfortKone™, Keratoconus Aspheric (paflucocon C) Rigid Gas Permeable  
Contact Lens for Daily Wear (Clear and Tinted)

Regulatory Class: II

Product Code: 86 HQD

Dated: March 23, 1999

Received: March 26, 1999

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

Enclosure

**INDICATIONS FOR USE STATEMENT**

**Device Name: ComfortKone™ Keratoconus Aspheric, (paflucocon C)  
Rigid Gas Permeable (RGP), Daily Wear Contact Lens  
(Clear and Tinted, Lathe-cut from Lens Blank)**

**INDICATIONS FOR USE:**

The ComfortKone™ Keratoconus Aspheric (paflucocon C) Rigid Gas Permeable (RGP) Daily Wear Contact Lens (Clear and Tinted, Lathe-cut from Lens Blank) is indicated for daily wear for persons requiring Keratoconus management with otherwise non-diseased eyes. The lens may be prescribed for the correction of refractive ametropia (myopia, hyperopia and astigmatism) in aphakic and not-aphakic persons. The lens may be disinfected with a chemical disinfection system.

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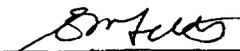
Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use   
(Per 21 CFR 801.109)

or

Over-The-Counter Use

(Optional Format 1-2-96)

  
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(Division Sign-Off)  
Division of Ophthalmic Devices  
510(k) Number K990264