K011893

DEC 0 6 2001

510(k) Summary
as required by 21 CFR 807.92(c)

1. **Submitted by:** Mr. Paolo Cociani
Contact Color Srl
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Date Summary prepared: 19 November 2001

2. **Device Name:** Common Name: Contact lens
Proprietary Name: Contact Color COSMETICA (Polymacon) soft (hydrophilic) contact lenses
Classification Name: Lenses, soft contact, daily wear

3. **Predicate Devices:**

Natural Touch (polymacon) Soft (hydrophilic) Contact Lens
510(k) number: K001089
Aspect Vision Care Ltd.
Unit 2, South Point
Hamble SO3 4RF
Southampton, United Kingdom

Ciba Vision Illusions (tefilcon) Soft (hydrophilic) Contact Lenses
PMA #810005/S25
Ciba Vision
11460 Johns Creek Parkway
Duluth, Georgia 30097, USA

4. **Description of Device:**

Contact Color COSMETICA (Polymacon) soft (hydrophilic) contact lenses are daily wear soft contact lenses for use in enhancing or altering the apparent color of the eye for prosthetic and theatrical use. The lenses used to produce Contact Color COSMETICA (Polymacon) soft (hydrophilic) contact lenses are Benz 38 (Polymacon) Soft (Hydrophilic) Daily Wear Contact Lens (Clear) supplied by Benz Research & Development of Sarasota, Florida. These lenses have received FDA premarket clearance (K961103). The Benz 38 lens material is polymacon, which in the hydrated state consists of 62% hydrophilic polymer of 2-hydroxyethylmethacrylate (2-HEMA) and 38% water. The Contact Color COSMETICA (Polymacon) soft (hydrophilic) contact lenses are made by incorporating by hand an opaque pigment in an iris pattern between two layers of the polymacon polymer.

5. **Intended Use Statement:**

The Contact Color COSMETICA (Polymacon) soft (hydrophilic) contact lenses are indicated for daily wear to enhance or alter the apparent color of the eye, including ocular masking, either in

sighted or non-sighted eyes that require a prosthetic contact lens for the cosmetic management of conditions such as scleral, corneal, iris, or lens abnormalities. The lens may also be prescribed for the correction of refractive ametropia (myopia and hyperopia) in aphakic and not aphakic persons or for occlusive therapy for conditions such as diplopia, amblyopia or extreme photophobia. The lenses may be disinfected using chemical disinfection systems.

6. Comparison with Predicate Devices:

Contact Color COSMETICA (Polymacon) soft (hydrophilic) contact lenses are substantially equivalent to the Aspect Vision Natural Touch (polymacon) Soft (hydrophilic) Contact Lens in that the hydrophilic material used is the same, which is 38% water content Polymacon, a nonionic polymer. They are also both daily wear contact lenses.

In contrast to the method of mixing the pigment with the polymer, which is used for the Natural Touch Soft Contact Lens, the color added to Contact Color COSMETICA (Polymacon) soft (hydrophilic) contact lenses is hand-painted on an inner lens surface and incorporated between two layers of polymacon polymer and therefore does not come into contact with the surface of the eye. This method of incorporating pigment between two polymer layers is similar to that described for the Ciba Vision Illusions contact lenses, which have received premarket approval from FDA.

Because of the incorporation of the pigment between two polymer layers, the internal and external lens surface remains smooth.

Characteristic	Contact Color COSMETICA (Polymacon) soft (hydrophilic) contact lenses	Aspect Vision Natural Touch (polymacon) Soft (hydrophilic) Contact Lens	Ciba Vision Illusions (tefilcon) Soft (hydrophilic) Contact Lenses
Indications for use	Daily wear in aphakic and not aphakic persons	Daily wear in not aphakic persons	Daily wear in not aphakic persons
Material	Polymacon (Benz 38 lenses)	Polymacon	Tefilcon
Material type	Nonionic polymer	Nonionic polymer	Nonionic polymer
Water content	38%	38%	37.5%
Light transmission	> 95%	> 97%	75.6 to 98%, depending upon over-tint
Dk (35°C)	9	8×10^{11}	9
Refractive index	1.43 (hydrated)	1.44 (hydrated)	1.43
Powers	+20 to –20	+6.00 to –10.00	+4 to –10
Pigments	Ultramarine blue, titanium dioxide, and iron oxides	Chromium-cobalt-aluminum oxide, titanium oxide and iron oxides	Opaque pigments are titanium dioxide, carmine, mica
Tint process	Incorporation of color, applied by hand, between polymer layers using FDA-cleared lens blanks; no over-tinting	Two stage print pad printing, pre-lens forming	Incorporation of color between polymer layers; then lenses are "over-tinted"

In consideration of the requirements of section 510(k) of the Federal Food Drug and Cosmetic Act, the Contact Color COSMETICA (Polymacon) soft (hydrophilic) contact lenses are substantially equivalent in terms of their safety and effectiveness to the Natural Touch (polymacon) Soft (hydrophilic) Contact Lens and the Ciba Vision Illusions (tefilcon) Soft (hydrophilic) Contact Lenses.

7. Performance Testing:

Contact Color COSMETICA (Polymacon) soft (hydrophilic) contact lenses were subjected to dye leachability testing and toxicology testing, including Acute Eye Irritation, Cytotoxicity, and Systemic Toxicity. The results of these tests demonstrated that the lenses are not susceptible to the migration of color from the lenses and that they are non-toxic. In addition, tests were conducted that verified the integrity of the interface bonding of the sandwich-configuration of the lenses.

8. Conclusion:

Based on the analysis of the comparison in section 6 above and the performance evaluation results contained in section 7, Contact Color Srl has concluded that Contact Color COSMETICA (Polymacon) soft (hydrophilic) contact lenses are safe, effective, and perform as well as the legally marketed devices identified in section 3 above.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 0 6 2001

Mr. Paolo Cociani
Managing Director
Contact Color SrL
Via L. di Monreale, 36
00152 Rome, Italy

Re: K011893
Trade/Device Name: Contact Color COSMETICA (polymacon)
Soft (hydrophilic) Contact Lenses
Regulation Number: 21 CFR 886.5925
Regulation Name: Soft (hydrophilic) Contact Lens
Regulatory Class: Class II
Product Code: LPL
Dated: October 26, 2001
Received: October 29, 2001

Dear Mr. Cociani:

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

510(k) Number: [not known]

Device Name: Contact Color COSMETICA (Polymacon) soft (hydrophilic) contact lenses

Indications for Use:

The Contact Color COSMETICA (Polymacon) soft (hydrophilic) contact lenses are indicated for daily wear to enhance or alter the apparent color of the eye, including ocular masking, either in sighted or non-sighted eyes that require a prosthetic contact lens for the cosmetic management of conditions such as scleral, corneal, iris, or lens abnormalities. The lens may also be prescribed for the correction of refractive ametropia (myopia and hyperopia) in aphakic and not aphakic persons or for occlusive therapy for conditions such as diplopia, amblyopia or extreme photophobia. The lens may be disinfected using chemical disinfection systems.

Concurrence of CDRH
Office of Device Evaluation
Division of Reproductive, Abdominal, ENT,
and Radiological Devices

(Division Sign-Off)
Division of Ophthalmic Devices
510(k) Number K011593

Prescription Use ✓ OR Over-The-Counter Use ____
(Per 21CFR 801.109)