

MAY 10 1999

510 (k) 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:

K984098

Applicant information:

Date Prepared:	November 12, 1998
Name:	Adventure in Color's
Address	1511 Washington Avenue Golden, CO 80401
Contact Person:	Mrs. Elizabeth Harper
Phone Number:	(303) 271-9644
USA Consultant:	Martin Dalsing, Med-Vice Consulting, Inc. Consultant for Adventure in Colors, Inc. 623 Glacier Drive Grand Junction, CO 81503 (970) 243-5490 Fax #: (970) 243-5501 E-mail: mdalsing@gj.net

Device Information:

Device Classification:	Class II
Classification Number:	LPL
Trade Name:	ADVENTURE TINTS, Color Enhanced Tinted Soft Contact lens
Classification Name:	Lenses, Soft Contact, Daily Wear

Substantially Equivalent Devices:

The “ADVENTURE TINTS” tinted soft contact lens is substantially equivalent to DURASOFT 2 COLORS tinted soft contact lens, the predicate device.

INDICATIONS FOR USE:

The ADVENTURE TINTS, Color Enhanced Tinted Soft Contact Lens is indicated for daily wear to enhance and/or alter the apparent eye color. The ADVENTURE TINTS visitint provides for ease of patient handling and does not effect iris color.

Except for decreased light transmittance due to the tint intensity, the pre-tinted lens optical parameters remain the same as originally prescribed for the user prior to tinting. The lens may be disinfected using a chemical disinfection system only.

Device Descriptive Characteristics:

ADVENTURE TINTS, Color Enhanced Tinted Soft Contact Lens are color enhanced soft contact lenses that have been previously prescribed for a specific patient. They have been supplied to Adventure in Colors to be modified by a tinting process using color additives that have been listed as safe for contact lenses in accordance with the FDA’s color additive regulations. The color additives are used in amounts not to exceed the minimum reasonably required to accomplish the intended coloring effect. As part of the manufacturing process, the lenses containing the color additives are thoroughly washed to remove unbound reactive color additives. The manufacturing process alters and/or changes the specifications to the clear version of a contact lens by affixing a listed color reactive additive on that portion of the anterior (front) surface of the lens that corresponds to the iris. The ADVENTURE TINTS, Color Enhanced Tinted Soft Contact Lens are available in a light, medium or dark shade of the following enhance colors; Blue, Deep Blue, Green, Aqua, Yellow, Lavender, Brown, Ultra Violet (Hot Pink), and Amber. ADVENTURE TINTS, Color Enhanced Tinted Soft Contact Lens are also available in a standard blue visibility-handling tint.

The color additive effect is formed by reacting one or more of the reactive color additives listed in this paragraph with (poly hydroxyethyl methacrylate). The reactive color additives that may be used either alone or in combination are: reactive black 5, reactive blue 21, reactive blue 19, reactive blue 4, reactive blue 163, reactive red 11, reactive red 180, reactive yellow 15, reactive yellow 86, or reactive orange 78. The color additives used are not removed by lens handling and cleaning/disinfecting procedures. Except for affecting the amount of light transmittance through the lens, the coloring process does not alter the original characteristics of the pre-tinted lens.

The following are tint patterns available to the practitioner:

- Clear Pupil diameter (2.00mm to 8.00mm), standard is 4.5mm.
- Annular (iris) diameter (8.00mm to 13.5mm), standard is 11.5mm diameter.
- Black pupil diameter (2.0mm to 12.5mm), standard is 4.0mm diameter.
- Occluder diameter (2.00mm to 12.5mm).

The following table summarizes Adventure in Colors claim of substantial equivalency in terms of safety and efficacy to the predicate device previously mentioned.

	Characteristic	ADVENTURE TINTS (Adventure in Colors)	Predicate Device
1.)	INTENDED USE	Daily wear, Soft (hydrophilic) contact lens	Daily wear, Soft (hydrophilic) contact lens
2.)	INDICATION	The ADVENTURE TINTS, Color Enhanced Tinted Soft Contact Lens is indicated for daily wear to enhance and/or alter the apparent eye color. The ADVENTURE TINTS visitint provides for ease of patient handling and does not effect iris color. Except for decreased light transmittance due to the tint intensity, the pre-tinted lens optical parameters remain the same as originally prescribed for the user prior to tinting. The lens may be disinfected using a chemical disinfection system only.	The Durasoft 2 Colors for daily wear are indicated for enhancing and/or altering the apparent eye color, including ocular masking.
3.)	ACTIONS	In its hydrated state, when placed on the cornea, the lenses act as a refracting medium to focus light rays on the retina.	In its hydrated state, when placed on the cornea, the lenses act as a refracting medium to focus light rays on the retina.
4.)	FDA "listed" colored additives	The reactive colored additives consist of reactive black 5, reactive blue 4, reactive blue 19, reactive 21, reactive blue 163, reactive yellow 15, reactive yellow 86, reactive orange 78, reactive red 11 and reactive red 180.	The colored pigments consist of iron oxides, chromium oxide greens, titanium dioxide, [phthalocyaninato (2-)] copper, carbazole violet and phthalocyanine green.
a.	Uses and restrictions	The color additives listed above may be used to color contact lenses in amounts not to exceed the minimum reasonably required to accomplish the intended coloring effect.	The color additives listed above may be used to color contact lenses in amounts not to exceed the minimum reasonably required to accomplish the intended coloring effect.
5.)	Color Additive Characteristics	The color additives used are not removed by lens handling and cleaning/disinfecting procedures. The optical and performance characteristics are not altered by the lens coloring process.	The color additives used are not removed by lens handling and cleaning/disinfecting procedures. The optical and performance characteristics are not altered by the lens coloring process.
6.)	Colors Offered	Blue, Green, Aqua, Yellow, Lavender, Brown, Ultra Violet (hot pink) and Amber	Sky blue, Jade green, Aquamarine and Violet blue

Table #1 – Substantial Equivalence



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

MAY 10 1999

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Martin Dalsing
Med-Vice Consulting, Inc.
Consultant for Adventure in Colors, Inc.
623 Glacier Drive
Grand Junction, CO 81503

Re: K984098

Trade Name: ADVENTURE TINTS, Color Enhanced Tinted Soft Contact lens for Daily Wear

Regulatory Class: II

Product Code: 86 LPL

Dated: March 30, 1999

Received: April 2, 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 handwritten signature in cursive script that reads "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 FOR USE STATEMENT

Device Name: **ADVENTURE TINTS, Color Enhanced Tinted Soft Contact lens**

INDICATIONS FOR USE:

The ADVENTURE TINTS, Color Enhanced Tinted Soft Contact Lens is indicated for daily wear to enhance and/or alter the apparent eye color. The ADVENTURE TINTS visitint provides for ease of patient handling and does not effect iris color.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)


(Division Sign-Off)

Division of Ophthalmic Devices

Prescription Use X
(Per 21 CFR 801.109)

510(k) Number K984098
or

Over-The-Counter Use

(Optional Format 1-2-96)

