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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: K992054

Applicant information:

Date Prepared:	June 18th, 1999
Name: Address	Adventure in Color's 1511 Washington Avenue Golden, CO 80401
Contact Persons:	Mrs. Elizabeth Harper Mr. Stan 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 PROSTHETIC** **Tinted Soft Contact lens**
Classification Name:	Lenses, Soft Contact, Daily Wear

Substantially Equivalent Devices:

The "ADVENTURE TINTS PROSTHETIC" Tinted Soft Contact Lens is substantially equivalent to the "Alden Classic Prosthetic Tinted Soft Contact Lens" and the Adventure in Colors "Adventure Tints Color Enhanced Tinted Soft Contact Lens", the predicate devices.

Device Descriptive Characteristics:

The ADVENTURE TINTS PROSTHETIC Tinted Soft Contact Lenses are tinted with FDA "listed" color additives. 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 reactive color additive on that portion of the anterior (front) surface of the lens that corresponds to the iris. The ADVENTURE TINTS PROSTHETIC contact lenses are tinted to the eyecare professional instructions.

The prosthetic 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 or approved cleaning/disinfecting procedures. The prosthetic lens tinting process does not alter the optical and/or performance characteristics of the finished tinted soft contact lens.

Tint Patterns Available:

1. **Clear lens with Black Pupil.** Pupil sizes available in 2.0 mm to 12.5 mm.
2. **Black Occluder Lens.** A Central Black area that occludes light. Available to full lens diameter in 0.5 mm increments.
3. **Black Annular with clear pupil.** Black Annular diameter range 7.5 mm to full lens diameter in 0.5 mm increments. Clear Pupil diameter range 2.0 mm to 7.5 mm in 0.5 mm increments.
4. **Tinted lens with Black Pupil.** Uses the Adventure Tints tinted contact lens with black pupil. Pupil sizes available in 2.0 mm to 12.5 mm diameter.

INDICATIONS FOR USE:

The ADVENTURE TINTS PROSTHETIC Tinted Soft Contact lens is indicated for daily wear to enhance or alter the apparent eye color, including ocular masking, either in sighted or non-sighted eyes that require a prosthetic contact lens for cosmetic management of conditions such as corneal, iris or lens abnormalities. The lens may also be prescribed for occlusive therapy for conditions such as diplopia, amblyopia or extreme photophobia. The lens may be disinfected using a chemical disinfection system only.

INDICATIONS FOR USE:

The ADVENTURE TINTS PROSTHETIC Tinted Soft Contact lens is indicated for daily wear to enhance or alter the apparent eye color, including ocular masking, either in sighted or non-sighted eyes that require a prosthetic contact lens for cosmetic management of conditions such as corneal, iris or lens abnormalities. The lens may also be prescribed for occlusive therapy for conditions such as diplopia, amblyopia or extreme photophobia.

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

	Characteristic	ADVENTURE TINTS (Adventure in Colors)	ALDEN CLASSIC PROSTHETIC (Predicate Device)
1.)	INTENDED USE	Cosmetic Management of conditions such as corneal, iris, or lens abnormalities.	Cosmetic Management of conditions such as corneal, iris, or lens abnormalities.
2.)	INDICATION	The ADVENTURE TINTS PROSTHETIC Tinted Soft Contact lens is indicated for daily wear to enhance or alter the apparent eye color, including ocular masking, either in sighted or non-sighted eyes that require a prosthetic contact lens for cosmetic management of conditions such as corneal, iris or lens abnormalities. The lens may also be prescribed for occlusive therapy for conditions such as diplopia, amblyopia or extreme photophobia. The lens may be disinfected using a chemical disinfection system only.	The ALDEN CLASSIC PROSTHETIC (polymacon) Tinted, Soft Contact Lens is indicated for daily wear to enhance or alter the apparent eye color, including ocular masking, either in sighted or non-sighted eyes that require a prosthetic contact lenses for cosmetic management of conditions such as corneal, iris or lens abnormalities. The lens may also be prescribed for the correction of refractive ametropia (myopia, hyperopia and astigmatism) in aphakic and not aphakic persons or for occlusive therapy for conditions such as diplopia, amblyopia or extreme photophobia. The lens may be disinfected with either a chemical or a heat disinfection system.
3.)	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.	Vat Green 1, Vat Brown 1, Vat Blue 6,
4.)	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 prosthetic 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 prosthetic effect.
5.)	Color Additive Characteristics	The color additives used are not removed by lens handling and approved 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 approved cleaning/disinfecting procedures. The optical and performance characteristics are not altered by the lens coloring process.

Table #1 – Substantial Equivalence

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL - 7 1999

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

Re: K992054
Trade Name: Adventure Tints Prosthethic Tinted Soft Contact Lens
Regulatory Class: II
Product Code: 86 LPL
Dated: June 17, 1999
Received: June 17, 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: **ADVENTURE TINTS PROSTHETIC**
Tinted Soft Contact lens

INDICATIONS FOR USE:

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(PLEASE DO OT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Daniel W. C. Brown, PhD

(Division Sign-Off)
Division of Ophthalmic Devices
510(k) Number K992054

Prescription Use X or Over-The-Counter Use ___
(Per 21 CFR 801.109)

(Optional Format 1-2-96)