JUN 3 ...

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: K990815

Applicant information:

Date Prepared:	March 12, 1999
Name: Address	Colorsoft Laboratories Corporation 623 Glacier Drive Grand Junction, CO 81503
Contact Person: Phone Number:	Ms. Deanna Werber President (970) 248-9445
USA Consultant:	Martin Dalsing, Med-Vice Consulting, Inc. Consultant for Colorsoft Laboratories Corporation 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:	**COLORSOFT, Color Enhanced Tinted Soft Contact lens for Daily Wear**
Classification Name:	Lenses, Soft Contact, Daily Wear

Substantially Equivalent Devices:

The "COLORSOFT" tinted soft contact lens is substantially equivalent to the DURASOFT 2 COLORS tinted soft contact lens, the predicate device.

INDICATIONS FOR USE:

The COLORSOFT, Color Enhanced Tinted Soft Contact Lens is indicated for daily wear to enhance and/or alter the apparent eye color. The COLORSOFT 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 is to be disinfected according to the original lens manufacturer's recommendation.

Device Descriptive Characteristics:

COLORSOFT, 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 Colorsoft Laboratories 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 COLORSOFT, Color Enhanced Tinted Soft Contact Lens are available in a light, medium or dark shade of the following enhance colors; Colorsoft Blue, Deep Blue, Aspen Green, Aquamarine, Yellow, Violet, Red, Chocolate, and Amber. COLORSOFT, 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.

The following table summarizes Colorsoft Laboratories claim of substantial equivalency in terms of safety and efficacy to the predicate devices previously mentioned.

1.)	**INTENDED USE**	Daily wear, Soft (hydrophilic) contact lens	Daily wear, Soft (hydrophilic) contact lens
2.)	**INDICATION**	The Colorsoft Choices Soft Contact Lenses for daily wear are indicated for enhancing and/or altering the apparent eye color. The Colorsoft Choices visitint provides for ease of patient handling and does not effect iris color. The lens is to be disinfected following the original manufacturer's instructions.	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, [phthalo-cyaninato (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 accompish 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 accompish 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**	Colorsoft Blue, Deep blue, Aspen Green, Jade, Aquamarine, Yellow, Violet, Red, Chocolate, and Amber	Sky blue, Jade green, Aquamarine and Violet blue

Table #1 – Substantial Equivalence

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 3 1999

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

Re: K990815
Trade Name: COLORSOFT, Color Enhanced Tinted Soft Contact lens for Daily Wear
Regulatory Class: II
Product Code: 86 LPL
Dated: March 12, 1999
Received: March 11, 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: **COLORSOFT, Color Enhanced Tinted Soft Contact lens for Daily Wear**

INDICATIONS FOR USE:

The COLORSOFT, Color Enhanced Tinted Soft Contact Lens is indicated for daily wear to enhance and/or alter the apparent eye color. The COLORSOFT visibility-handling tint 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 is to be disinfected according to the original lens manufacturer's recommendation.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Daniel W. C. Brown, PH.D.

(Division Sign-Off)
Division of Ophthalmic Devices

510(k) Number K990815

Prescription Use X
(Per 21 CFR 801.109)

Over-The-Counter Use ___

(Optional Format 1-2-96)