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: K991995

Applicant information:

Date Prepared:	11 June, 1999
Name:	Softchrome, Inc.
Address	2551 San Ramon Valley Blvd., Suite #105 San Ramon, CA 94583
Contact Person:	Mrs. Karen L. Johnson
Phone Number:	(925) 743-1285
U.S. Consultant:	Martin Dalsing Med-Vice Consulting, Inc. Official Correspondent Softchrome, 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, MZD
Trade Name:	**SOFTCHROME TINTS** **Transparent Tinted Soft Contact Lens**
Classification Name:	Lenses, Soft Contact, Daily Wear

Substantially Equivalent Devices:

The SOFTCHROME TINTS Transparent Tinted Soft Contact Lens is substantially equivalent to the Adventure Tints Color Enhanced Soft Contact Lens, the predicate device.

INDICATIONS FOR USE:

The SOFTCHROME TINTS, Color Enhanced Tinted Soft Contact Lens is indicated for daily wear to enhance and/or alter the apparent eye color. The SOFTCHROME TINTS visibility tinted lens provides for ease of patient handling and does not affect 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:

SOFTCHROME TINTS Transparent Tinted Soft Contact Lens are color enhanced soft contact lenses that have been previously prescribed for a specific patient. The lenses are tinted with utilization of the patented "In-Office Tinting System for Soft Contact Lenses". The tinting system consists of various tinting fixtures, calibrated mixing vessels, pre-mixed color additives, activator solution, neutralizer solution, tinting instructions, tips and recipes. The lens tinting process uses 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 additive on that portion of the anterior (front) surface of the lens that corresponds to the iris. The In-Office Tinting System for Soft Contact Lenses offers a variety of colors and intensity levels. The SOFTCHROME TINTS Transparent Tinted Soft Contact Lens is also available in a variety of colors for 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 approved 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 table summarizes Softchrome Inc. claim of substantial equivalency in terms of safety and efficacy to the predicate devices previously mentioned.

	Characteristic	Softchrome Tints (Softchrome Inc.)	Adventure Tints (Predicate Device)
1.)	INTENDED USE	Daily wear, Soft (hydrophilic) contact lens	Daily wear, Soft (hydrophilic) contact lens
2.)	INDICATION	The SOFTCHROME TINTS, Transparent Tinted Soft Contact Lens is indicated for daily wear to enhance and/or alter the apparent eye color. The SOFTCHROME TINTS visitint provides for ease of patient handling and does not affect 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 ADVENTURE TINTS Color Enhanced 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 affect 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.
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 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.
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	Aqua, Blue, Sky Blue, Green, Brown, Black, Green, Yellow, Amber and Red	Blue, Green, Aqua, Yellow, Lavender, Brown, Ultra Violet (hot pink) and Amber

Table – Substantial Equivalence

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 27 1999

Softchrome, Inc.
c/o Mr. Martin Dalsing
Med-Vice Consulting, Inc.
623 Glacier Drive
Grand Junction, CO 81503

Re: K991995
Trade Name: SOFTCHROME TINTS, Transparent Tinted Soft Contact lens (tinted with the "In-Office Tinting System for Soft Contact Lenses")
Regulatory Class: II
Product Code: 86 MZD
Dated: June 11, 1999
Received: June 14, 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: **SOFTCHROME TINTS Transparent Tinted Soft Contact lens**

INDICATIONS FOR USE:

The SOFTCHROME TINTS, Color Enhanced Tinted Soft Contact Lens is indicated for daily wear to enhance and/or alter the apparent eye color. The SOFTCHROME TINTS visibility tinted lens provides for ease of patient handling and does not affect 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.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

(Optional Format 1-2-96)

Howard W. C. Brown Ph.D
(Division Sign-Off)
Division of Ophthalmic Devices
510(k) Number K991995