OCT 2 0 2000

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: **K994320**

Applicant information:

Date Prepared:	October 1, 2000
Name:	Cantor & Silver Limited
Address	Market Place Brackley Northants England NN13 7DP
Contact Person:	Mr. David Cantor Managing Director/President
Phone Number:	011 44 1280 702002
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USA Consultant:	Martin Dalsing, Med-Vice Consulting, Inc. Consultant for Cantor & Silver, 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, NCZ
Trade Name:	**ChromaGen $_{V2.0}$ Haploscopic System & Color Discrimination Enhancement Soft Contact Lens**
Classification Name:	Lens, Soft Contact, Daily Wear

SUMMARY BASIS for Substantial Equivalence ~

Substantially Equivalent Devices:

The **ChromaGen $_{V2.0}$ Color Discrimination Enhancement Soft Contact Lenses** are substantially equivalent to the "X-Chrom" RED Tinted PMMA Contact Lens" and the Cantor & Silver "CANTOR & SILVER 5X Tinted", the predicate devices.

NOTE: The "X-Chrom" RED Tinted lens is classified as a pre-amendment device.

Device Descriptive Characteristics:

The **ChromaGen $_{V2.0}$ Color Discrimination Enhancement** filters are designed specifically to improve discrimination between colors that are normally confused by people with protan or deutan (red-green) color vision deficiencies

The **ChromaGen $_{V2.0}$ Color Discrimination Enhancement Soft Contact Lenses** are a range of soft contact lenses with precision tinted pupils of varying hue and saturation which, when used monocular and binocularly, have been shown to be of use in patients with defective color vision. Use of this product may enhance the discrimination of certain colors and may reduce the discrimination of certain colors. This device in not a cure for color vision deficiencies or colorblindness.

The **ChromaGen $_{V2.0}$ Color Discrimination Enhancement 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 lens 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 **ChromaGen $_{V2.0}$ Color Discrimination Enhancement Soft Contact Lenses** are tinted to the eyecare professional instructions.

The ChromaGen 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 **ChromaGen $_{V2.0}$ Haploscopic System & Color Discrimination Enhancement Soft Contact Lenses** tinting process *does not* alter the optical and/or performance characteristics of the finished tinted soft contact lens.

PRECAUTION FOR CHROMAGEN LENSES

Special precaution for ChromaGen practitioners regarding the possible alterations in spatial perception.

Patients using the darker shades of tint in their ChromaGen lenses may experience some or all of the following:

- reduced low contrast acuity,
- reduced illumination at night,
- distortions in distance perception of moving objects or while driving,
- distortions of apparent velocity.

Thus, wearing these darker lenses may make driving difficult, especially at night, or under foggy, misty, or other adverse conditions.

INDICATIONS FOR USE STATEMENT

The **ChromaGen $_{V2.0}$ Haploscopic System & Color Discrimination Enhancement Soft Contact Lenses** are indicated for daily wear to enhance color discrimination in patients with protan or deutan (red-green) color vision deficiencies. The lens may also be prescribed for the correction of refractive ametropia (myopia, hyperopia and astigmatism) in aphakic and not aphakic persons with non-diseased eyes. The lenses are disinfected using a hydrogen peroxide lens care system only and are available in a frequent replacement program.

SUBSTANTIAL EQUIVALENCE TABLE

The following table summarizes Cantor & Silver Limited claim of substantial equivalency in terms of safety and efficacy to the predicate devices previously mentioned.

	Characteristic	ChromaGen V2.0	X-CHROM LENS (pre-amendment device)	Cantor & Silver 5X Prosthetic
1.)	**INDICATION for USE**	The **ChromaGen V2.0 Haploscopic System & Color Discrimination Enhancement Soft Contact Lenses** are indicated for daily wear to enhance color discrimination in patients with protan or deutan (red-green) color vision deficiencies. The lens may also be prescribed for the correction of refractive ametropia (myopia, hyperopia and astigmatism) in aphakic and not aphakic persons with non-diseased eyes. The lenses are disinfected using a hydrogen peroxide lens care system only and are available in a frequent replacement program.	Correction of color-blindness particularly red-green color blindness. NOTE: Not regulated (pre-amendment device)	The Cantor & Silver 5X Prosthetic Tinted Soft Contact Lenses are 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 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 lenses are disinfected using a hydrogen peroxide lens care system only and are available in a frequent replacement program.
2.)	**Production Method**	Lathe-Cut	Lathe-cut	Lathe-cut
3.)	**Contact Lens Material**	hydrophilic	PMMA	hydrophilic
3.)	**FDA Listed Color 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.	Not Available	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.
4.)	**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.	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.
5.)	**Use 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.	Not Available	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.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 2 0 2000

Mr. Martin Dalsing
Consultant for Cantor & Silver Limited
c/o Medvice Consulting, Inc.
623 Glacier Drive
Grand Junction, CO 81503

Re: K994320
Trade Name: The ChromaGen$_{V2.0}$ Haploscopic System & Color Discrimination Enhancement Soft Lenses
Regulatory Class: II
Product Code: 86 NCZ
Dated: August 21, 2000
Received: August 24, 2000

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) 594-6413. 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 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/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

K994320

INDICATIONS FOR USE STATEMENT

Device Name: **ChromaGen $_{V2.0}$ Haploscopic System & Color Discrimination Enhancement 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)

Steve Helmantoller
(Division Sign-Off)
Division of Ophthalmic Devices
510(k) Number K994320

Prescription Use X
(Per 21 CFR 801.109)

or

Over-The-Counter Use ___

(Optional Format 1-2-96)