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510 (k) SUMMARY

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: **K012132**

Applicant information:

Date Prepared:	April 12, 2001
Name: Address	Cantor & Nissel Limited Market Place Brackley Northants England NN13 7DP
Contact Person:	Mr. David Cantor Managing Director
USA Consultant:	Martin Dalsing, Medvice Consulting, Inc. Consultant and US Agent for Cantor & Nissel, Ltd. 623 Glacier Drive Grand Junction, CO 81503 (970) 243-5490 Fax #: (970) 243-5501 E-mail: mdalsing@FDApproval.com

Device Information:

Device Classification:	Class II
Classification Number:	886.5925
Trade Name:	**ChromaGen $_{V3.0}$ Reading Aid Soft Contact Lens**
Reason for 510(k) submission:	Expanded Indication to K990757, K994320
Classification Name:	Lens, Soft Contact, Daily Wear

Substantially Equivalent Devices:

The **ChromaGen $_{V3.0}$ Reading Aid, Soft Contact Lenses** are substantially equivalent to the following legally marketed devices:

1. Cantor & Nissel "CANTOR & NISSEL 5X Tinted", tinted contact lens Re: K990757

2. Cantor & Nissel "ChromaGen $_{V2.0}$ Color Discrimination Enhancement, Soft Contact Lenses" tinted contact lens Re: K994320

Device Descriptive Characteristics:

The **ChromaGen $_{V3.0}$ Reading Aid, Soft Contact Lenses** are a range of soft lenses with precision tinted pupils of varying hue and saturation which, when used in combination, have been shown to be of use for patients experiencing visual discomfort when reading. The **ChromaGen $_{V3.0}$ Reading Aid, 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 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 $_{V3.0}$ Reading Aid, Soft Contact Lenses** tinting process *does not* alter the optical and/or performance characteristics of the finished tinted soft contact lens.

INDICATIONS FOR USE:

The **ChromaGen $_{V3.0}$ Reading Aid Soft Contact Lenses** are indicated for daily wear for the correction of refractive ametropia (myopia, hyperopia and astigmatism) in aphakic and not-aphakic persons with non-diseased eyes.

Theses lenses may also be prescribed as a colored filter to aid individuals who experience reading discomfort not related to binocular vision problems or uncorrected refractive error. The lenses are disinfected using a hydrogen peroxide lens care system only and are available in a frequent replacement program.

Preclinical Studies

The biocompatibility testing, compatibility testing, physical and optical parameters of the lens can be referenced in K990757 & K994320.

Clinical Testing

The **ChromaGen Reading Aid, Soft Contact Lens** are lenses that have the pupil area tinted with one of a variety of colors. A clinical study was carried out to evaluate these colored lenses as an aid for patients who ewxperience visual discomfort while reading. Fifty-three subjects who had reading difficulties entered into the study. They ranged in age from 9 to 40. (Patients were selected from those responding to press coverage.) Subjects were excluded if their own eyecare professional indicated that they had any underlying optometric cause for reading difficulties. Forty-seven subjects completed the study.

Subjects were tested to determine which color filters from the ChromaGen diagnostic set gave the least distortion or made the print "easiest to read" (subjectiviely). The study used placebo lenses, which were clear (light handling tint) contact lenses that the patients were told had been specially treated to make the color invisible to the naked eye. Patients were given various short paragraphs to read aloud. These consisted of simple words placed in random order (not sentences). Each patient read some of these paragraphs: (1) without lenses (2) with ChromaGen lenses, and (3) with placebo contact lenses. The order of lens use was randomized. Subjects were asked to grade the subjective improvement in "ease of reading" and were asked which type of lens they preferred. Of the 40 subjects who espressed an opinion, 29 (72.5 per cent) preferred ChromaGen lenses to the placebo lenses. Six subjects chose not to give a response and 1 rated the two lenses equal. The median "ease of reading" grading (scale from –10 to +10) was 7.0 for the ChromaGen lenses and was 4.5 for the placebo lenses. Analysis of these results (Wilcoxon) shows that ChromaGen lenses were rated very significantly more highly than the placebo lenses ($p<0.001$)."

Table of Substantial Equivalence

	Characteristic	ChromaGen Reading Aid lenses (subject device)	Cantor & Nissel ChromaGen Color Discrimination lenses (K994320) (predicate device)	Cantor & Nissel Tinted lenses (K990757) (predicate device)
1.)	**INDICATION for USE**	The ChromaGen V3.0 Reading Aid Soft Contact Lenses are indicated for daily wear for the correction of refractive ametropia (myopia, hyperopia and astigmatism) in aphakic and not-aphakic persons with non-diseased eyes. Theses lenses may also be prescribed as a colored filter to aid individuals who experience reading discomfort not related to binocular vision problems or uncorrected refractive error. The lenses are disinfected using a hydrogen peroxide lens care system only and are available in a frequent replacement program.	The ChromaGen V2.0 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.	The Cantor & Nissel 5X 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. The lens may also be prescribed for the correction of refractive ametropia (myopia, hyperopia and astigmatism) in aphakic and not aphakic persons. The lenses are disinfected using a hydrogen peroxide lens care system only and are available in a frequent replacement program.
2.)	**Efficacy**	Established, Clinical study	Established, Clinical study	Established Pre-clinical studies
3.)	**Device**	Colored Filter Contact Lens (lathe-cut)	Colored Filter Contact Lens (lathe-cut)	Colored Filter Contact Lens (lathe-cut)
4.)	**Device Material**	Soft Contact Lens (hydrophilic)	Soft Contact Lens (hydrophilic)	Soft Contact Lens (hydrophilic)
5.)	**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.	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.
6.)	**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.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 0 9 2002

Cantor & Nissel, Ltd.
c/o Martin Dalsing
Medvice Consulting, Inc.
623 Glacier Drive
Grand Junction, CO 81503

Re: K012132/S002
Trade/Device Name: ChromaGen$_{V3.0}$ Reading Aid Soft Contact Lens
Regulation Number: 886.5925
Regulation Name: Soft (hydrophilic) contact Lens
Regulatory Class: Class II
Product Code: NIC; LPL
Dated: April 9, 2002
Received: April 16, 2002

Dear Mr. Dalsing:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate 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) that do not require approval of a premarket approval application (PMA). 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 (PMA), 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 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 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 21 CFR Part 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" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer 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

K012132

INDICATIONS FOR USE STATEMENT

Device Name: **ChromaGen $_{V3.0}$ Reading Aid, Soft Contact Lens**

INDICATIONS FOR USE:

The **ChromaGen $_{V3.0}$ Reading Aid Soft Contact Lenses** are indicated for daily wear for the correction of refractive ametropia (myopia, hyperopia and astigmatism) in aphakic and not-aphakic persons with non-diseased eyes.

Theses lenses may also be prescribed as a colored filter to aid individuals who experience reading discomfort not related to binocular vision problems or uncorrected refractive error. The lenses are disinfected using a hydrogen peroxide lens care system only and are available in a frequent replacement program.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Karen Warburton

(Division Sign-Off)
Division of Ophthalmic Ear,
Nose and Throat Devises

510(k) Number K012132

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

(Optional Format 1-2-96)