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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: *K022373*

### **Applicant information:**

Date Prepared: June 27, 2002

Name: Cantor & Nissel Limited  
Address: 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@FDAapproval.com

### **Device Information:**

Device Classification: Class I

Regulation Number: 886.5844

Product Code: NJH, HQG, NAI

Trade Name: **ChromaGen<sub>v3.0</sub> Reading Aid & Color Discrimination Enhancement Spectacle Lenses**

Reason for 510(k) submission: Expanded Device classification to K994320 & K012132

Classification Name: Prescription Spectacle lens

***Substantially Equivalent Device:***

The **ChromaGen v3.0 Reading Aid & Color Discrimination Enhancement, Spectacle Lenses** are substantially equivalent to the following legally marketed devices:

Cantor & Nissel “ChromaGen v3.0 Reading Aid, Soft Contact Lenses”  
A tinted contact lens Re: K012132

Cantor & Nissel “ChromaGen v2.0 Color Discrimination Enhancement, Soft Contact Lenses”  
A tinted contact lens Re: K994320

***Device Descriptive Characteristics:***

The **ChromaGen v3.0 Reading Aid & Color Discrimination Enhancement, Spectacle Lenses** are prescription spectacles that have been precision coated with varying hue and saturation filters similar to antireflection coatings and colored prescription sunglass coatings that are already included in the prescription spectacle lens classification. **ChromaGen v3.0 Reading Aid & Color Discrimination Enhancement** are available in varying hues and saturation levels duplicate of that available in the **ChromaGen v3.0 Reading Aid & Color Discrimination Enhancement, Soft Contact Lenses**. The **ChromaGen v3.0 Reading Aid & Color Discrimination Enhancement, Spectacle Lens** has been designed for binocular use, and when used in combination, have been shown to be of use for patients experiencing visual discomfort when reading.

The **ChromaGen v3.0 Reading Aid & Color Discrimination Enhancement, Spectacle Lens** coating/tinting process *does not* alter the optical and/or performance characteristics of the finished spectacle lens.

***INDICATIONS FOR USE:***

Prescribed for the correction of refractive ametropia (myopia, hyperopia and astigmatism) in aphakic and not-aphakic persons.

Prescribed as a colored filter to aid individuals who experience reading discomfort not related to binocular vision problems or uncorrected refractive error.

Prescribed to enhance color discrimination in patients with protan or deutan (red-green) color vision deficiencies.

**Summary Basis for Substantial equivalence**

**ChromaGen v3.0 Reading Aid & Color Discrimination Enhancement, Spectacle Lenses to ChromaGen v3.0 Reading Aid & Color Discrimination Enhancement Contact Lenses:**

**ChromaGen v3.0 Reading Aid & Color Discrimination Enhancement, Spectacle Lenses** are prescription spectacle lenses coated/tinted to the exact same spectacle light transmittance as the predicate device soft contact lens. Clinical performance studies are not required for the spectacle version of the **ChromaGen v3.0 Reading Aid & Color Discrimination Enhancement** product line, as efficacy has been established in K994320 & K012132.

Table of Substantial Equivalence

	Characteristic	ChromaGen Reading Aid, Spectacle Lenses (subject device)	ChromaGen Reading Aid, Soft Contact Lenses (predicate device)	ChromaGen Color Discrimination Enhancement, Soft Contact Lenses (predicate device)
1.)	<b>INDICATION for USE</b>	The ChromaGen v3.0 Reading Aid & Color Discrimination, Spectacle Lenses are prescription spectacle lenses that are indicated for the correction of refractive ametropia (myopia, hyperopia and astigmatism) in aphakic and not-aphakic persons. The ChromaGen V3.0 Reading Aid spectacle 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 ChromaGen V3.0 Color Discrimination Enhancement spectacle lenses may also be prescribed to enhance color discrimination in patients with protan or deutan (red-green) color vision deficiencies.	The ChromaGen v3.0 Reading Aid Soft Contact Lenses are indicated for daily wear as an aid for patients who experience visual discomfort when reading. 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. These 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 any hydrogen peroxide lens care system or the Purilens system, and are available in a frequent replacement program.
2.)	<b>Efficacy</b>	Substantially Equivalent, Clinical study (reference K994320 & K012132)	Established, Clinical study K012132	Established, Clinical study K994320
3.)	<b>Device Classification</b>	Class I	Class II	Class II
4.)	<b>Device type</b>	Spectacle Lens	Soft Contact Lens	Soft Contact Lens



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

OCT 07 2002

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

Re: K022373  
Trade Name: ChromaGen v3.0 Reading Aid & Color Discrimination  
Enhancement Spectacle Lenses  
Classification Regulation Number: 886.5844  
Regulation Name: Prescription Spectacle lens  
Regulatory Class: I  
Product Code: NJH, HQG, NAI  
Dated: June 27, 2002  
Received: July 22, 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, M.D.  
Director  
Division of Ophthalmic and Ear,  
Nose and Throat Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

**INDICATIONS FOR USE STATEMENT**

**Device Name:**                    **ChromaGen v3.0 Reading Aid & Color Discrimination  
Enhancement, Spectacle Lenses**

***INDICATIONS FOR USE:***

Prescribed for the correction of refractive ametropia (myopia, hyperopia and astigmatism) in aphakic and not-aphakic persons.

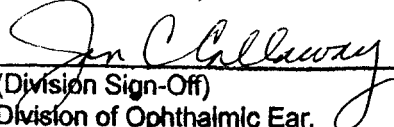
Prescribed as a colored filter to aid individuals who experience reading discomfort not related to binocular vision problems or uncorrected refractive error.

Prescribed to enhance color discrimination in patients with protan or deutan (red-green) color vision deficiencies.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number     K022373    

**Prescription Use**   
(Per 21 CFR 801.109)

or

**Over-The-Counter Use**

(Optional Format 1-2-96)