4/21/99

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: K990757

Applicant information:

Date Prepared:	March 12, 1999
Name:	Cantor & Silver Limited
Address	Manor Road, Brackley Northamptonshire England NN13 6ED
Contact Person:	Mr. David Cantor Managing Director/President
Phone Number:	011 44 1280 702002
Fax:	011 44 1280 703003
Official Correspondent: And US Consultant	Med-Vice Consulting, Inc. Mr. Martin Dalsing President/CCO 623 Glacier Grand Junction, CO 81503
Phone Number:	970.243.5490
Fax Number:	970.243.5501

Device Information:

Regulatory Classification:	Class II
Product Code:	86 LPL
Trade Name:	**CANTOR & SILVER 5X Tinted (hioxifilcon A) Soft (Spherical & Toric) Daily Wear Contact Lens, Tinted.**
Classification Name:	Lenses, Soft Contact, Daily Wear

Equivalent Device:

The CANTOR & SILVER 5X Tinted (hioxifilcon A) Soft (Spherical & Toric) Daily Wear Contact Lens is substantially equivalent to the predicate device in terms of intended use and design. The predicate device is the Durasoft 2 Colors manufactured by Wesley-Jessen.

Device Description:

The CANTOR & SILVER 5X Tinted (hioxifilcon A) Soft (Spherical & Toric) Daily Wear Contact lens are fabricated from hioxifilcon A, which in the dry (unhydrated) state may be machined and polished. The hydrophilic nature of this material allows the lens to become soft and pliable when immersed in an aqueous solution. The color enhanced soft contact lenses are tinted with "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 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 tinted contact lenses are available in a light, medium or dark shade of the following enhance colors; Blue, Green, Aqua, Yellow, Lavender, Brown, Ultra Violet, and Amber.

The color additive (tinting) effect is formed by reacting one or more of the "listed" additives with HEMA based (poly hydroxyethyl methacrylate) soft contact lens. The color additives used are not removed by lens handling and cleaning/disinfecting procedures as recommended. Except for affecting the amount of light transmitted through the lens, the coloring process does not alter the original characteristics of the pre-tinted lens.

In the hydrated state, the lens conforms to the curvature of the eye covering the cornea and extending slightly beyond the limbus forming a transparent optical surface. The (hioxifilcon A) soft hydrophilic contact lens has a spherical back surface. The hydrophilic properties of the lens require that it be maintained in a fully hydrated state in a solution compatible with the eye. If the lens dries out, it will become hard and appear somewhat warped; however, it will return to its proper configuration when completely rehydrated in the proper storage solution.

The hydrophilic characteristics allow aqueous solutions to enter the lens and in its fully hydrated state the lens is approximately 58% water by weight.

The non-ionic lens material, hioxifilcon A is an ultra high molecular weight copolymer of 2-hydroxyethyl methacrylate (2-HEMA) and 2,3-Dihydroxypropyl Methacrylate (Glycerol Methacrylate, GMA) and cross-linked with ethylene glycol dimethacrylate (EGDMA). It consists of 42% hioxifilcon A and 58% water by weight when immersed in normal saline solution buffered with sodium bicarbonate. The physical properties of the lens are:

Refractive Index	1.515 (dry) 1.404 (hydrated)
Light Transmission (tinted)	greater than 70%
Color Additives	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
Water Content	58 % ± 2%
Specific Gravity	1.308 (dry) 1.136 (hydrated)
Oxygen Permeability	20 X 10^{-11} (cm^2/sec) (ml O_2/ml x mm Hg @ 35°C), (revised Fatt method).

INDICATED USE:

The **CANTOR & SILVER 5X Tinted (hioxifilcon A) Spherical** Soft Contact Lenses for daily wear are indicated for the correction of visual acuity in aphakic and not-aphakic persons with non-diseased eyes with myopia or hyperopia. The lenses may be worn by persons who exhibit refractive astigmatism of 1.50 diopters or less where the astigmatism does not interfere with visual acuity. The lenses are disinfected using a hydrogen peroxide lens care system only, and are available in a frequent replacement program.

The **CANTOR & SILVER 5X Tinted (hioxifilcon A) Toric** Soft Contact Lenses for daily wear are indicated for the correction of visual acuity in aphakic and not-aphakic persons with non-diseased eyes with myopia or hyperopia and/or possesses refractive astigmatism up to 10.00 diopters. The lenses are disinfected using a hydrogen peroxide lens care system only, and are available in a frequent replacement program.

Substantial Equivalence:

The device will be manufactured according to specified process controls and a Quality Management System certified to ISO 9002 and EN46002 by the National Accreditation of Certification Bodies. The device will undergo manufacturing, packaging and sterilization procedures similar to devices currently marketed and distributed by Cantor & Silver Limited in the United States. The established safety profile (pre-clinical toxicology and manufacturing/chemistry data) of the device is equivalent to the BENZ-G 5X (hioxifilcon A), 510(k) #K952620. The tinting characteristics and parameters of the lens are substantially equivalent to the Durasoft 2 Colors tinted soft contact lens, manufactured Wesley-Jessen. Being similar with respect to indications for use, materials, physical construction and safety & effectiveness to the predicate device, this meets the requirements per section 510(k) of the act regarding substantial equivalence and ***does not raise*** different questions of safety and effectiveness than the predicate devices identified above.

The following matrix illustrates that the production method, lens function, and the "listed" color additives and tinting characteristics of the CANTOR & SILVER 5X Tinted (hioxifilcon A) Soft (Spherical & Toric) Daily Wear Contact Lens are substantially equivalent to the predicate device.

Substantial Equivalence Matrix

	Characteristic	CANTOR & SILVER 5X TINTED	DURASOFT 2 COLORS
1.)	PRODUCTION METHOD	Lathe-Cut	Lathe-Cut
2.)	LENS FUNCTION	Refractive medium that focuses light rays from near and distant objects on the retina, while compensating for refractive error, including (astigmatism)	Refractive medium that focuses light rays from near and distant objects on the retina, while compensating for refractive error, including (astigmatism)
3.)	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, [phthalocyaninato (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 accomplish 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 accomplish the intended coloring effect.
4.)	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.
5.)	Colors Offered	Blue, Green, Aqua, Yellow, Lavender, Brown, Ultra Violet and Amber	Sky blue, Jade green, Aquamarine and Violet blue

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 2 1 1999

Mr. Martin Dalsing
Med. Vice Consulting, Inc.
623 Glacier Drive
Grand Junction, CO

Re: K990757
Trade Name: Cantor & Silver 5X Tinted (hioxifilcon A) Soft Contact Lens
Regulatory Class: II
Product Code: 86 LPL
Dated: April 7, 1999
Received: April 12, 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: **CANTOR & SILVER 5X TINTED (hioxifilcon A) Soft (Spherical & Toric) Daily Wear Contact Lens, Tinted.**

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The **CANTOR & SILVER 5X Tinted (hioxifilcon A) Toric** Soft Contact Lenses for daily wear are indicated for the correction of visual acuity in aphakic and not-aphakic persons with non-diseased eyes with myopia or hyperopia and/or possesses refractive astigmatism up to 10.00 diopters. 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)

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

(Optional Format 1-2-96)

(Division Sign-Off)
Division of Ophthalmic Devices

510(k) Number K990757