JUL 3 0 2004

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: K041700

Applicant information:

Date Prepared:	June 1, 2004
Name:	Cantor & Nissel Limited
Address	Manor Road, Brackley Northamptonshire England NN13 7DP
Contact Person:	Mr. David Cantor Managing Director/President
Phone Number:	011 44 1280 702002
Fax:	011 44 1280 703003
USA Consultant:	Martin Dalsing, Med-Vice Consulting, Inc. Consultant for Cantor & Nissel, Inc. 623 Glacier Drive Grand Junction, CO 81503 (970) 243-5490 Fax #: (970) 243-5501 E-mail: Marty@FDApproval.com

Device Information:

Device Classification:	Class II
Classification Number:	LPL
Trade Name:	**Cantor & Nissel Hand Painted Prosthetic (hioxifilcon A) Soft Contact Lens for Daily Wear**
Classification Name:	Lens, Soft Contact, Daily Wear

Substantially Equivalent Devices:

The "**Cantor & Nissel Hand Painted Prosthetic (hioxifilcon A) Soft Contact Lens for Daily Wear**" is substantially equivalent to the "Prosthetic (hefilcon A) Soft Lens ~ K992950".

Device Descriptive Characteristics:

The **Cantor & Nissel Hand Painted Prosthetic (hioxifilcon A) Soft Contact Lens for Daily Wear** is a hand painted lens with an iris pattern to mask a disfiguring or unsightly eye condition. The lens may be partially opaque for a non-sighted eye or clear in the center for a sighted eye. Lens opacity is obtained by tinting the lenses with FDA "listed" color additives in amounts not to exceed the minimum reasonably required to accomplish the intended iris pattern. The colorants are permanent and are not leached from a lens. The lenses are painted by skilled artists to an eye care practitioners specifications.

INDICATIONS FOR USE:

The **Cantor & Nissel Hand Painted Prosthetic (hioxifilcon A) Soft Contact Lens for Daily Wear** is 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 lens is disinfected using a hydrogen peroxide lens care system only.

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

	Characteristic	CANTOR & NISSEL Hand Painted PROSTHETIC	Prosthetic (hefilcon A) Soft Contact Lens ~ K992950
1.)	**INTENDED USE**	Cosmetic Management of conditions such as corneal, iris, or lens abnormalities.	Cosmetic Management of conditions such as corneal, iris, or lens abnormalities.
2.)	**INDICATIONS FOR USE STATEMENT**	The CANTOR & NISSEL Hand Painted PROSTHETIC (hioxifilcon A) Soft Contact Lens 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 lens is disinfected using a hydrogen peroxide lens care system only.	The Prosthetic (hefilcon A) Soft Contact Lens is 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 lenses 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 lens may be disinfected with a chemical disinfection system.
3.)	**OPACITY**	One or more FDA listed color additives	Partially or totally White
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.
5.)	**OPAQUING AGENT USED**	Use of FDA listed reactive dyes in amounts to accomplish desired hand painted iris patterns.	Titanium Dioxide

Table #1 – Substantial Equivalence

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 3 0 2004

Cantor & Nissel Ltd.
c/o Martin Dalsing
Med-Vice Consulting, Inc.
623 Glacier Dr.
Grand Junction, CO 81503

Re: K041700
Trade/Device Name: Cantor & Nissel Hand Painted Prosthetic (hioxifilcon A) Soft Contact Lens for Daily Wear
Regulation Number: 21 CFR 886.5925
Regulation Name: Soft (hydrophilic) contact lens
Regulatory Class: Class II
Product Code: LPL
Dated: June 1, 2004
Received: June 23, 2004

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), please contact the Office of Compliance at (301) 594-4613. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act 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

Enclosure

INDICATIONS FOR USE STATEMENT

Device Name: **Cantor & Nissel Hand Painted Prosthetic (hioxifilcon A) Soft Contact Lens for Daily Wear**

INDICATIONS FOR USE:

The **Cantor & Nissel Hand Painted Prosthetic (hioxifilcon A) Soft Contact Lens for Daily Wear** is 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 lens is disinfected using a hydrogen peroxide lens care system only.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Daniel W. Brown, Ph.D.

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

510(k) Number K041700

Prescription Use JS X
(Per 21 CFR 801.109)

or

Over-The-Counter Use ___

(Optional Format 1-2-96)