MAY 12 2006

510 (K) Summary

K053191

SUMMARY OF SAFETY AND EFFECTIVENESS
FOR
Discon Daily (Etafilcon A) One-Day Soft (hydrophilic) Contact Lens

Submitter Information:

Company:	INNOVA VISION INC. No. 231-1, Wen-Te Road, Chiung-lin Village, Hsin-Chu County, Taiwan.
Contact Person:	Mr. Michael w. Hsu Executive Vice President
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Date Prepared	Oct. 20, 2005

Identification of Device:

Classification Name:	Soft hydrophilic contact lens, per 21 CFR. 886.5925
Trade Name:	Discon Daily (Etafilcon A) One-Day Soft (hydrophilic) Contact Lens
Common or usual Name:	Soft (hydrophilic) Contact lens (daily wear)
FDA Classification:	Class II
Registration Number	3003746024

Predict Device:

Discon (Etafilcon A) Soft (hydrophilic) Contact Lens for Daily Wear cleared via K051129 from Innova Vision Corp., Taiwan.
Acuvue Brand (Etafilcon A) Soft (hydrophilic) Contact Lens for Daily Wear cleared via K013973 from Johnson & Johnson Vision Care, Inc. USA.

Indications for Use:

Discon Daily (Etafilcon A) One-Day Soft (hydrophilic) Contact Lens is indicated for the correction of visual acuity in not-aphakic persons with non-diseased eyes that are myopia or hyperopia and may exhibited refractive astigmatism up to 2.00 diopters that does not interfere with visual acuity. The eye care practitioner may prescribe the contact lens for single-use daily disposable wear.

Description of Device:

Discon daily Contact Lens are available as non-spherical lenses manufactured by spin-casting method. The model illuminated with high water content (58 %). The hydrogel lens' material is a random copolymer composed of 2-hydroxyethyl methacrylate (HEMA) and methacrylic acid (MAA), which was cross-linked with 1,1,1-trimethylolpropane trimethacrylate (TMPTMA) and Ethylene Glycol Dimethacrylate (EGDMA) via UV photo- polymerization. The Discon Daily Contact lens with visible tint is light tinted blue using Reactive Blue Dye #19 to make the lens more visible for handling. Lenses are supplied sterile in sealed blister packers containing sterile isotonic phosphate buffered saline. The compatibility and package integrity of the blister pack packaging system has been demonstrated and successfully used for other marketed lens products, and packaged lenses are effectively steam-sterilized in a validated autoclave.

Clinical Studies:

The 510(k) describes a labeling modification to the "Wearing Schedual" section of the Package Insert and to the "introduction" section of the Patient Instruction and professional fitting Guide for Daily disposable Wear. There is no change in lens material, the manufacturing process, nor the parameter and properties therefore, the clinical data previously submitted in K051129 supports the clinical safety of the subject device. There is a slightly exchange of blue-tint concentration in the polymer composition.

Discon Daily lenses have been wide-used around the world, including Taiwan, China, etc. Among the users being daily worn the Discon Daily lenses, all the procedures were in generally stable condition without severe complication. There are no significant side effects and complaints to be observed.

Nonclinical Studies:

Non-clinical studies (chemistry, toxicology, microbiology, shelf-life and leachability) on the lens material were not conducted since the lens material (Etafilcon A) and manufacturing process do not change as compared with our own product- Discon (Etafilcon A) Soft (hydrophilic) Contact Lens for Daily Wear cleared via K051129.

a) Technological characteristics studies

Discon Daily contact lens designs in the following parameter ranges:

Diameter range; 13.8 to 14.2 mm

Power range: +6.00D to –12.00D

Center thickness: varies with power (0.08 to 0.12 mm for –3.00D)

Lenses have the following properties:

Refractive index: 1.407 (hydrated)

Light transmittance: >93%

Water content: 56 to 60 %

Oxygen permeability (edged corrected) : 24×10^{-11} [(cm^2/sec)(ml O_2/ml-mmHg)] @ 35℃

These technological characteristics of Discon Daily Contact lenses do not change to that of predicate lenses previously submitted in K051129.

Substantial equivalence Statement:

Testing performed on the Discon Daily (Etafilcon A) One-Day Soft (hydrophilic) Contact Lens indicated that it can support the efficiency and security use as well as the predicate devices- Discon (Etafilcon A) Soft (hydrophilic) Contact Lens for Daily Wear (K051129) & ACUVUE (Etafilcon A) Contact Lens visibility tint- K013973), when used in accordance with the instructions for use. It is due to the facts that the risks and benefits of the subject device are the same as soft contact lenses for to the daily wear.

In conclusion, it is Innova's conviction that data submitted in this 510(k) to validate the claim of substantial equivalency, substantiates our ability to manufacture a soft contact lens, the Discon Daily (Etafilcon A) One-Day Soft (hydrophilic) Contact Lens, with the same established safety profile and effectiveness as the predicate device-- Discon (Etafilcon A) Soft (hydrophilic) Contact Lens for Daily Wear (K051129) & ACUVUE (Etafilcon A) Contact Lens visibility tint (K013973).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 12 2006

Innova Vision Inc.
c/o Ms. Jennifer Reich
Harvest Consulting Corp
2904 N. Boldt Drive
Flaggstaff, Az 86001

Re: K053191
Trade/Device Name: Discon Daily (Etafilcon A) One-Day Soft (hydrophilic) Contact Lens
Regulation Number: 21 CFR 886.5925
Regulation Name: Soft (hydrophilic) Contact lens (daily wear)
Regulatory Class: II
Product Code: MVN; LPL
Dated: April 17, 2006
Received: April 20, 2006

Dear Ms. Reich:

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) 827-8910. 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/industry/support/index.html.

Sincerely yours,

Malvina B. Eydelman, 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

510(k) Number: K053191

Device Name: Discon Daily (Etafilcon A) One-Day Soft (hydrophilic) Contact Lens

Indications for Use:

Discon Daily (Etafilcon A) One-Day Soft (hydrophilic) Contact Lens is indicated for the correction of visual acuity in not-aphakic persons with non-diseased eyes that are myopia or hyperopia and may exhibited refractive astigmatism up to 2.00 diopters that does not interfere with visual acuity.

The eye care practitioner may prescribe the contact lens for single-use daily disposable wear. The Discon Daily Lenses are not intended to be disinfected and should be discarded after a single use.

Prescription Use X OR Over-The-Counter _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Ming-Chuen Shih

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

510(k) Number K053191