NOV 18 1999

510(k) #K992950

510(k) SUMMARY

Applicant Information:

Date Prepared:	August 26, 1999
Submitted by:	Prosthetic Soft Lens Company 2890 South Tejon Street Englewood, CO 80110
Contact Person:	William Hoffman
Phone:	303-789-0933
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Email:	lagado@lagado.net

Device Information:

Trade Name:	Prosthetic (hefilcon A) Soft Lens
Classification Name:	Lens, Soft Contact, Daily Wear
Class and Number:	Class II, LPL

Substantially Equivalent to:

(1) Prosthetic (polymacon) Hydrophilic Contact Lens, K984259
(2) Classic Prosthetic (polymacon), K983053
(3) Oxylens tinted Prosthetic (hioxifilcon B), K983278

Device Description:

The Prosthetic (hefilcon A)Soft Lens is a partially or totally white opaque lens that is painted or printed with an iris or other pattern to mask a disfiguring or unsightly eye condition. The lens may be totally opaque for a non-sighted eye or clear in the center for a sighted eye. The approved pigment, titanium dioxide, is incorporated into the lens matrix as the white opaquing agent. Lenses are printed or painted by skilled artists to a eye care practitioners specifications with approved reactive dyes. The opaquing agent and colorants are permanent and are not leached from a lens.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 18 1999

Mr. William Hoffman
President
Prosthetic Soft Lens Corporation
2890 South Tejon Street
Englewood, CO 80110

Re: K992950
Trade Name: Prosthetic (hefilcon A) Soft Contact Lens
Product Code: 86 LPL
Dated: September 8, 1999
Received: September 14, 1999

Dear Mr. Hoffman:

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

510(k) NUMBER (IF KNOWN): **K992950**

DEVICE NAME: Prosthetic (hefilcon A) Soft Contact Lens

INDICATIONS FOR USE:

The Prosthetic (hefilcon A) Soft Contact Lens is indicated for daily wear to enhance or alter the appearance of the eye, including ocular masking, in sighted or non-sighted eyes, that may require a prosthetic contact lens for the cosmetic management of corneal, iris, scleral or lens abnormalities; or for persons wishing to change the appearance of their eyes without eye abnormalities. The lens may also be prescribed for the correction of refractive ametropia (myopia, hyperopia or astigmatism) in aphakic or non-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.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Daniel W C Brown

(Division Sign-Off)
Division of Ophthalmic Devices
510(k) Number K992950

JS

Prescription Use X
(Per 21 CFR 801.109)

Over-The-Counter Use _____
(Optional Format 1-2-96)