

SUMMARY
 ESSTECH® MULTI Aspheric (multifocal)
 (hioxifilcon B) Soft (hydrophilic) Contact Lens

1. Submitted by: Les Laboratoires Blanchard
 Lentilles De Contact
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2. Date prepared: August 3, 1998

3. Device:
 Common Name ESSTECH® MULTI Aspheric (multifocal)
 (hioxifilcon B)Soft (hydrophilic)
 Contact Lens
 Trade Name ESSTECH® MULTI Aspheric (multifocal)
 (hioxifilcon B)Soft (hydrophilic)
 Contact Lens

4. Classification Class II (Performance Standards)
 21 CFR 886.5925, 86LPL
 Lenses, Soft Contact, Daily Wear

5. Substantial equivalence This lens is made in hioxifilcon B, the same material as cited in K964528 (Mar 10, 1997) and is identical in design to the ESSTECH® PS Aspheric (polymacon) Soft (hydrophilic) Contact Lens, P910029/S1 (June 29, 1993).

6. Device description The ESSTECH® MULTI Aspheric (multifocal) (hioxifilcon B) Soft (hydrophilic) Contact Lens is available as a lens with an aspheric front surface for the correction of visual acuity in presbyopic persons who are myopic or hyperopic. The lens is constructed to provide optimum edge thickness and contour, with the central area providing the reading power in the equivalent of a 2.00 diopter near addition. The aspheric front curve undergoes a progressive power change, resulting in intermediate and distance power outward from the center. The lens is a flexible transparent shell of the following dimensions:

K982904, Esstech® Multi

Chord diameter: 14.0/14.5mm
Center thickness: 0.07 to 0.15mm
Base Curve: 8.30 and 8.80mm
Power: -5.00D to +9.00D (in 0.25D steps)

The lens material, hioxifilcon B, is a hydrophilic co-polymer of glycerol methacrylate (GMA) and 2-hydroxyethyl methacrylate (2-Hema), crosslinked with ethylene glycol dimethacrylate. The lens is swollen to equilibrium state in sterile buffered saline solution, and contains 48% water by weight when fully hydrated.

7. Indications for Use

The ESSTECH® MULTI Aspheric (multifocal) (hioxifilcon B) Soft (hydrophilic) Contact Lens is indicated for daily wear for the correction of refractive ametropia (myopia, hyperopia and/or presbyopia) in not-aphakic persons with non-diseased eyes. The lens may be worn by persons who may exhibit astigmatism of 1.50 diopters or less that does not interfere with visual acuity.

The lens may be disinfected using either heat (thermal) or chemical (not heat) disinfection systems.

8. Comparison to predicate device: see following table
SUBSTANTIAL EQUIVALENCE

	BENZ-G 3X Sphere & Toric (K964528) hioxifilcon B	Esstech® Multi Asphere (K982904) hioxifilcon B
Material		
Refractive index	1.404, hydrated	1.404, hydrated
Light transmittance	>95% clear >95% blue tint	>95% clear >95% blue tint
Surface characteristics	hydrophilic, hemispherical shell; toric lens has a toric base curve	hydrophilic, spherical back curve, aspheric front curve
Water content	48% by weight in normal buffered saline	48% by weight in normal buffered saline
Oxygen permeability	15 (cm ² /sec)(ml O ₂ /ml x mmHg@35°C) (revised Fatt method)	15 (cm ² /sec)(ml O ₂ /ml x mmHg@35°C) (revised Fatt method)

K982904, Esstech® Multi

9. Chemistry and Manufacturing

This lens is made in hioxifilcon B, the same material as cited in K964528 (Mar 10, 1997) and is identical in design to the ESSTECH® PS Aspheric (polymacon) Soft (hydrophilic) Contact Lens, P910029/S1 (June 29, 1993). Contained in this submission are references to K964528 and MAF-816 for the manufacture of the lens material, to P910029/S1 for the manufacture, packaging and sterilization of the lens, a report of the manufacture of 10 lenses to prescription, and draft labeling.

Ten (10) ESSTECH® MULTI Aspheric (multifocal) (hioxifilcon B) Soft (hydrophilic) Contact Lenses were manufactured according to prescription, and shown to be within acceptable standards by the ordering clinician. The report is attached.

10. Toxicology

All toxicology is contained in K964528.

11. Microbiology

Lens manufacturing, packaging and sterilization are identical to the manufacturing, packaging and sterilization described for the ESSTECH® PS Aspheric approved in PMA P910029,S1, therefore sterilization validation is not required.

12. Clinical Studies

All clinical information is contained in K964528.

13. Shelf-Life 1 year, as established in K964528.



SEP 1 1998

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Les Laboratories Blachard
c/o John M. Szabocsik, Ph.D.
SZABOCSIK AND ASSOCIATES
203 North Wabash Avenue
Suite 1200
Chicago, IL 60601

Re: K982904

Trade Name: ESSTECH® MULTI Aspheric (multifocal) (hioxifilcon B) Soft (hydrophilic)
Contact Lens (clear and blue visibility tint, lathe-cut)

Regulatory Class: II

Product Code: 86 LPL

Dated: August 14, 1998

Received: August 18, 1998

Dear Dr. Szabocsik:

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.

Page 2 - Dr. John M. Szabocsik, Ph.D.

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) K982904

DEVICE NAME ESSTECH® MULTI Aspheric (multifocal)
(hioxifilcon B) Soft (hydrophilic)
Contact Lens

INDICATIONS FOR USE

The ESSTECH® MULTI Aspheric (multifocal) (hioxifilcon B) Soft (hydrophilic) Contact Lens is indicated for daily wear for the correction of refractive ametropia (myopia, hyperopia and/or presbyopia) in not-aphakic persons with non-diseased eyes. The lens may be worn by persons who may exhibit astigmatism of 1.50 diopters or less that does not interfere with visual acuity.

The lens may be disinfected using either heat (thermal) or chemical (not heat) disinfection systems.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use
(Per 21 CFR 801.109)

OR

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

LSO
(Division Sign-Off)
Division of Ophthalmic Devices
510(k) Number K982904

JS