

K990281

APR 16 1999

K990281, FOI Summary

510(k) SUMMARY FOR FOI

S-38™ (polymacon) Soft (hydrophilic) Contact Lens,
Esstech® PS (polymacon) Soft (hydrophilic) Contact Lens,
Esstech® SV (polymacon) Soft (hydrophilic) Contact Lens, all with
blue tint

Classification Name: Contact Lens

Common/Usual Name: Contact Lens

Proprietary Name: S-38™ (polymacon) Soft (hydrophilic)
Contact Lens, the Esstech® PS
(polymacon) Soft (hydrophilic) Contact
Lens and the Esstech® SV (polymacon)
Soft (hydrophilic) Contact Lens

Establishment Registration Number: 9610790
Owner/Operator No: 8010037

Classification: Contact lenses were reclassified as Class II
devices in November, 1993.
21 CFR 886.5925, 86LPL

Performance Standards: None

Labeling: Copies of labeling, revised to include the
presence of the blue tint, were included in
this submission.

Substantial Equivalence: The sponsor considers these lenses to be
substantially equivalent to the S-38™
Soft (polymacon) Contact Lens covered in
the approved PMA 920036 and the Esstech®
PS (polymacon) Soft (hydrophilic)
Contact Lens and the Esstech® SV
(polymacon) Soft (hydrophilic) Contact
Lens covered in the 510(k)'s K942186 and
K942187, respectively.

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SUBSTANTIAL EQUIVALENCE
S-38™

Material	S-38™ Clear Untinted	S-38™ Blue Tinted
Description	hydrophilic polymer of 2-hydroxyethyl methacrylate cross-linked with ethyleneglycol dimethacrylate	hydrophilic polymer of 2-hydroxyethyl methacrylate cross-linked with ethyleneglycol dimethacrylate containing the dye Procion blue MX-R.
Water Content	38%	same
Refractive Index	1.43, hydrated	same
Light Transmittance (visible)	>97%	>95%
Oxygen permeability	$D_k = 8.5$ (cm/sec)(ml O_2 /mlxmm Hg) Measured at 35°C (Fatt method).	same
Actions	When placed on the human cornea, the hydrated lens acts as a corrective refracting medium to focus light rays on the retina.	same
Chord Diameter	12.5 to 15.0 mm	same
Center thickness	0.07 to 0.97 mm	same
Base Curve	7.40 to 9.60 mm	same
Powers	-20.00 to +20.00 D	same

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SUBSTANTIAL EQUIVALENCE
ESSTECH® PS

Material	ESSTECH® PS Clear Untinted	ESSTECH® PS Blue Tinted
Description	hydrophilic polymer of 2-hydroxyethyl methacrylate cross-linked with ethyleneglycol dimethacrylate	hydrophilic polymer of 2-hydroxyethyl methacrylate cross-linked with ethyleneglycol dimethacrylate containing the dye Procion blue MX-R.
Water Content	38%	same
Refractive Index	1.43, hydrated	same
Light Transmittance (visible)	>97%	>95%
Oxygen permeability	$D_k = 8.5 (\text{cm/sec})(\text{ml O}_2/\text{mlxmm Hg})$ Measured at 35°C (Fatt method).	same
Actions	When placed on the human cornea, the hydrated lens acts as a corrective refracting medium to focus light rays on the retina.	same
Chord Diameter	14.00 ± 0.20 mm	same
Center thickness	0.17 ± 0.02 mm	same
Base Curve	8.30, 8.70, and 9.10 ± 0.10 mm	same
Powers	+10.00 to -10.00D in 0.25 dioptric steps	same

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SUBSTANTIAL EQUIVALENCE
ESSTECH® SV

Material	ESSTECH® SV Clear Untinted	ESSTECH® SV Blue Tinted
Description	hydrophilic polymer of 2-hydroxyethyl methacrylate cross- linked with ethyleneglycol dimethacrylate	hydrophilic polymer of 2-hydroxyethyl methacrylate cross- linked with ethyleneglycol dimethacrylate containing the dye Procion blue MX-R.
Water Content	38%	same
Refractive Index	1.43, hydrated	same
Light Transmittance	>97%	>95%
Oxygen permeability	$D_k = 8.5(\text{cm/sec})(\text{ml}$ $\text{O}_2/\text{mlxmm Hg})$ Measured at 35°C (Fatt method).	same
Actions	When placed on the human cornea, the hydrated lens acts as a corrective refracting medium to focus light rays on the retina.	same
Chord Diameter	14.00 ± 0.20 mm	same
Center thickness		
Minus powers:	0.07 to	same
Variable from	0.14 ± 0.02 mm	same
Plus powers:		
Variable from	0.15 to	same
	0.30 ± 0.02 mm	
Base Curve	8.30, 8.70, and 9.10 ±0.10 mm	same
Powers	+10.00 to -10.00D in 0.25 dioptric steps	same

SUMMARY

PRODUCT DESCRIPTION AND CHEMISTRY

The lenses are identical to the already approved and cleared products S-38™ (polymacon) Soft (hydrophilic) Contact Lens, the Esstech® PS (polymacon) Soft (hydrophilic) Contact Lens and the Esstech® SV (polymacon) Soft (hydrophilic) Contact Lens, except for the addition of the listed color additive Procion Blue MX-R (Reactive Dye Blue #4).

TOXICOLOGY:

The lenses passed cytotoxicity, systemic toxicity and ocular irritation testing.

MICROBIOLOGY

All microbiological testing is contained in P920036.

CLINICAL DATA

Since there is no change other than the addition of a listed color additive, no new clinical data was generated. All prior clinical data is contained in P920036.

MANUFACTURING

The blue tinted lenses are manufactured in a manner identical to that described in P920036, K942186 and K942187, with the addition of the tinting process.



APR 16 1999

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NISSEL LIMITED
c/o John M. Szabocsik, Ph.D.
203 North Wabash Avenue
Suite 1200
Chicago, IL 60601

Re: K990281

Trade Name: S-38™ (polymacon) Soft (hydrophilic) Contact Lens, the Esstech® PS
Lens and the Esstech® SV (polymacon) Soft (hydrophilic) Contact Lens,
With blue tint

Regulatory Class: II
Product Code: 86 LPL
Dated: January 26, 1999
Received: January 28, 1999

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 (Pre-market 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) K990281

DEVICE NAME S-38™ (polymacon) Soft (hydrophilic) Contact Lens, the Esstech® PS (polymacon) Soft (hydrophilic) Contact Lens and the Esstech® SV (polymacon) Soft (hydrophilic) Contact Lens, with blue tint

INDICATIONS FOR USE

The S-38™ (polymacon) Soft (hydrophilic) Contact Lens with blue tint is indicated for daily wear for the correction of visual acuity in aphakic and not-aphakic persons with non-diseased eyes that are myopic or hyperopic. 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 Esstech® PS (polymacon) Soft (hydrophilic) Contact Lens, with blue tint is indicated for daily wear for the correction of visual acuity in not-aphakic persons with non-diseased eyes that are myopic or hyperopic presbyopes. The lens may be worn by persons who may exhibit astigmatism of not more than 2.00 diopters that does not interfere with visual acuity.

The Esstech® SV (polymacon) Soft (hydrophilic) Contact Lens, with blue tint is indicated for daily wear for the correction of visual acuity in not-aphakic persons with non-diseased eyes that are myopic, hyperopic and/or marginally presbyopic requiring up to +1.00 D of add. The lens may be worn by persons who exhibit astigmatism of 1.50 diopters or less but may not be suitable for higher degrees of astigmatism.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter-Use _____
(Per 21 CFR 801.109) (Optional Format 1-2-96)

Samuel W. Brown Ph.D.
(Division Sign-Off)
Division of Ophthalmic Devices
510(k) Number K990281