

K991780

JUN 29 1999

510(K) SUMMARY FOR FREEDOM OF INFORMATION

Addition of UV blocker to Fluorex® 700, 500, 300
(flusilfocon A, B, C) Material
for Rigid Permeable Contact Lenses

1. Submitted by: G. T. Laboratories, Inc
2007 Johns Drive
Glenview, IL 60025-1616

- Contact Person: John M. Szabocsik, Ph.D.
Szabocsik and Associates
203 N. Wabash, Ste 1200
Chicago, IL 60601
TEL: 312-553-0828

2. Date Prepared May 18, 1999

3. Common/Usual Contact Lens

4. Proprietary Name Fluorex® 700-UV (flusilfocon A),
Fluorex® 500-UV (flusilfocon B),
Fluorex® 300-UV (flusilfocon C),
Rigid Gas Permeable Contact Lenses

5. Device Description The UV blocking materials contain a
UV-absorbing compound incorporated
into the fluoro-silicate-acrylic-
copolymers (flusilfocon A, B, C).
The Fluorex® UV (flusilfocon) Rigid
Gas Permeable Contact Lens when
placed on a cornea acts as a
refracting medium to focus light
rays onto the retina.

6. Intended Use The spherical lens is intended to
be used in the correction of visual
acuity in eyes that are myopic or
hyperopic. Bifocal and trifocal
designs are available for the
correction of visual acuity in eyes
that are also presbyopic.

7. Equivalence: The sponsor considers these lenses
to be substantially equivalent to
Fluorex® 700 (flusilfocon A) Rigid
Gas Permeable Contact Lenses,
approved under PMA #P880001. The
attached table summarizes the
comparison of the new materials to
the predicate device.

SUBSTANTIAL EQUIVALENCE

Material Type	Fluorex® 700	Fluorex® 700- UV	Fluorex® 500	Fluorex® 500- UV	Fluorex® 300	Fluorex® 300-UV
Material Description	Fluoro-silicate-acrylic-copolymers. Tinted lenses contain one or more of the following dyes: D&C Green dye #6, D&C Yellow dye #10. D&C Violet #2, D&C Red dye #17, CI Solvent Yellow 18. The UV absorbing lenses also contain Cyasorb UV-416					
Actions	When placed on the human cornea, the hydrated lens acts as a corrective refracting medium to focus light rays on the retina.					
Chord Diameter*	←————— 7.00 to 10.50 mm —————→					
Center thickness*	←————— 0.10mm to 1.00mm —————→					
Base Curve*	←————— 6.00 to 9.00 mm —————→					
Powers*	←————— -20.00 to +12.00 D —————→					
Gas permeability (D _k) (polarographic method)	70.0	70.0	50.0	51.5	30.0	29.3
Hardness (Shore D hardness ANZI/ASTM)	85.5	85.5	86.5	86.5	87.0	87.0
Wetting Angle (Wilhelmy plate method)	14.8°	14.8°	13.8°	13.8°	12.9°	12.9°
Water content (ANZI Z80.6; 5.6.1)	All materials <1.0%					
Refractive Index (ANZI/ASTM D542-20)	1.457	1.457	1.460	1.460	1.465	1.464
Specific Gravity	1.097	1.085	1.110	1.110	1.118	1.119
Light Transmission, Visible (380-780nm) Clear lens (ANZI/ASTM 280.6.4.5)	All materials >90%					
Light Transmission, UV (250-350nm) Clear lens (ANZI/ASTM 280.6.4.5)	All UV absorbing materials 0.0%					

*Parameters for spherical lenses

CHEMISTRY

The Fluorex® -UV (flusilfocon) materials are rigid gas permeable materials for making contact lenses, consisting of a fluorine-containing polyacrylate-silicone blend, and identical to the already approved Fluorex® (flusilfocon) materials in component monomers, with the only difference being the addition of the UV blocker. No monomers were found to be extracted from the material.

TOXICOLOGY

The Fluorex® UV (flusilfocon) material was found to be noncytotoxic in an agar overlay cytotoxicity test.

MICROBIOLOGY

No testing was required, based on the similarity to the predicate device

CLINICAL

No testing was required, based on the similarity to the predicate device



JUN 29 1999

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

G.T. Laboratories, Inc.
C/O John M. Szabocsik, Ph.D.
203 North Wabash Avenue Suite 1200
Chicago, IL 60601

Re: K991780

Trade Name: Fluorex® 700-UV (flusilfocon A), Fluorex® 500-UV (flusilfocon B) and Fluorex® 300-UV (flusilfocon C) Rigid Gas Permeable Contact Lenses

Regulatory Class: II

Product Code: 86 HQD

Dated: May 21, 1999

Received: May 25, 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.

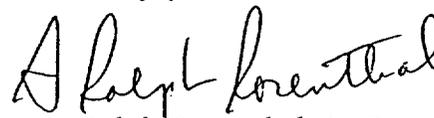
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially 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 - 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) K991780

DEVICE NAME Fluorex® 700-UV (flusilfocon A),
Fluorex® 500-UV (flusilfocon B) and
Fluorex® 300-UV (flusilfocon C) Rigid
Gas Permeable Contact Lenses

INDICATIONS FOR USE

The Fluorex® 700-UV (flusilfocon A), Fluorex® 500-UV (flusilfocon B) and Fluorex® 300-UV (flusilfocon C) Spherical Rigid Gas Permeable Contact Lenses are indicated for daily wear for the correction of visual acuity in not-aphakic persons with non-diseased eyes that are myopic, hyperopic and which may exhibit astigmatism of 1.50 diopters or less that does not interfere with visual acuity.

The Fluorex® 700-UV (flusilfocon A), Fluorex® 500-UV (flusilfocon B) and Fluorex® 300-UV (flusilfocon C) Translating Bifocal and Trifocal Contact Lenses are indicated for daily wear for the correction of visual acuity in not-aphakic persons with non-diseased presbyopic eyes that are myopic or hyperopic and which may exhibit astigmatism of 3.50 diopters or less that does not interfere with visual acuity.



(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)

David W. C. Brown, Ph.D.

(Division Sign-Off)
Division of Ophthalmic Devices

510(k) Number K991780