K991781

510(K) SUMMARY FOR FREEDOM OF INFORMATION

JUN 29 1999

Fluorex® Ultra (flusilfocon E) 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 17, 1999
3. Common/Usual	Contact Lens
4. Proprietary Name	Fluorex® Ultra (flusilfocon E) Rigid Gas Permeable Contact Lenses
5. Device Description	The lens material (flusilfocon E), is a fluoro-silicate-acrylic-copolymer. The Fluorex® Ultra (flusilfocon E) 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 material to the predicate device.

SUBSTANTIAL EQUIVALENCE
Fluorex® Ultra compared to Fluorex® 700

Material Type	Fluorex® 700	Fluorex® Ultra
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.	
Gas permeability (D_k) (polarographic method)	70.0	60.0
Hardness (Shore D hardness ANZI/ASTM)	85.5	86.0
Wetting Angle (Wilhelmy plate method)	15.3°	13.9°
Water absorption (ANZI Z80.6; 5.6.1)	<1.0%	<1.0%
Refractive Index (ANZI/ASTM D542-20)	1.457	1.458
Specific Gravity	1.097	1.103
Light Transmission, (ANZI/ASTM 280.6.4.5)	88.1% (clear) 75.0% (gray) 74.9% (blue) 72.6% (green)	>70% (aqua)
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	0.10 to 1.00 mm	
Base Curve	6.00 to 9.00 mm	
Powers	-20.00 to +12.00 D	

*Parameters for spherical lenses

CHEMISTRY

The Fluorex® Ultra (flusilfocon E) material is a rigid gas permeable material for making contact lenses, consisting of a fluorine-containing polyacrylate-silicone blend, identical to the already approved Fluorex® 700 (flusilfocon A) material in component monomers, with differences only in the relative proportion of each component, which results in the difference in gas permeability (D_k). No monomers were found to be extracted from the material.

TOXICOLOGY

The Fluorex® Ultra (flusilfocon E) 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

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 29 1999

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

Re: K991781
Trade Name: Fluorex® Ultra (flusilfocon E) Rigid Gas Permeable Contact Lens
Regulatory Class: II
Product Code: 86 HQD
Dated: May 17, 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.

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) K991781

DEVICE NAME Fluorex® Ultra (flusilfocon E) Rigid Gas Permeable Contact Lens

INDICATIONS FOR USE

The Fluorex® Ultra (flusilfocon E) 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® Ultra (flusilfocon E) 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)

Daniel W. C. Brown, Ph.D.

(Division Sign-Off)
Division of Ophthalmic Devices
510(k) Number K991781