



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Gelflex Laboratories
c/o Don Ezekiel, AM OD
General Manager
3 Hutton Street Osborne Park
Perth Western Australia 6017

APR 01 2003

Re: K030027

Trade/Device Name: The Gelflex Synergy (hioxifilcon B) Soft Contact Lens for Daily Wear (Spherical and Toric in clear or blue visitint; Lathe-cut)
The Gelflex (hioxifilcon B) Soft Contact Lens for Daily Wear
(Triton Translating Bifocal and Triton Translating Toric Bifocal in clear or blue visitint; lathe-cut)

Regulation Number: 21 CFR 886.5925

Regulation Name: Soft (hydrophilic) Contact Lens

Regulatory Class: Class II

Product Code: LPL

Dated: December 4, 2002

Received: January 3, 2003

Dear Dr. Ezekiel:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate 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) that do not require approval of a premarket approval application (PMA). 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 (PMA), 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 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 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), please contact the Office of Compliance at (301) 594-4613. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,

A handwritten signature in cursive script that reads "A. Ralph Rosenthal".

A. Ralph Rosenthal, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

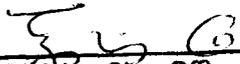
Enclosure

Indications for use statement

The Gelflex Synergy (hioxifilcon B) Soft Contact Lens (spherical and toric in both clear or blue visitint) is indicated for daily wear for the correction of refractive ametropia (myopia or hyperopia) in aphakic or non-aphakic persons with non-diseased eyes. The Gelflex Synergy (hioxifilcon B) Spherical Lens may be worn by persons who have astigmatism of 1.50 diopters or less which does not interfere with visual acuity. The Gelflex Synergy (hioxifilcon B) Toric Lens may be worn by persons who have astigmatism of up to 4.50 diopters.

The Gelflex (hioxifilcon B) Soft Contact Lens (Triton Translating Bifocal and Triton Translating Toric Bifocal in both clear or blue visitint) is indicated for daily wear for the correction of distance and near vision in presbyopic aphakic and non-aphakic persons with non-diseased eyes. The Gelflex (hioxifilcon B) Triton Translating Bifocal Lens may be worn by persons who have astigmatism of 0.50 diopters or less which does not interfere with visual acuity. The Gelflex (hioxifilcon B) Triton Translating Toric Bifocal Lens may be worn by persons who have astigmatism of up to 6.00 diopters.

The lenses may only be prescribed for daily wear and must be cleaned and disinfected as recommended by the eye care practitioner. The lenses may be disinfected using chemical (not heat) or hydrogen peroxide disinfection systems as recommended by your care practitioner.



(Division Sign-Off)
Division of Ophthalmic Ear,
Nose and Throat Devices
510(k) Number K030027

Prescription Use 

(Per 21 CFR 801.109)