DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

March 19, 2013

Soflex Limited
% Mr. Kevin Walls, RAC
Principal Consultant
Regulatory Insight, Inc.
33 Golden Eagle Lane
Littleton, CO 80127

Re: K122220
Trade/Device Name: Eni-Eye SH Soft K Semi Scleral (Efrofilcon A) Soft (hydrophilic) Keratoconus and Irregular Cornea Contact Lens for Daily Wear and Eni-Eye SH Soft K Toric Semi Scleral (Efrofilcon A) Soft (hydrophilic) Keratoconus and Irregular Cornea Contact Lens for Daily Wear
Regulation Number: 21 CFR 886.5925
Regulation Name: Soft (hydrophilic) contact lens
Regulatory Class: Class II
Product Code: LPL
Dated: March 7, 2013
Received: March 8, 2013

Dear Mr. Walls:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Kesia Y. Alexander -S

for Malvina B. Eydelman, 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

510(k) Number (if known): K122220

Device Name: Eni-Eye SH Soft K Semi Scleral (Efrofilcon A) Soft (hydrophilic) Keratoconus and Irregular Cornea Contact Lens for Daily Wear

Indications for Use: The Eni-Eye SH Soft K Semi Scleral (Efrofilcon A) Soft (hydrophilic) Keratoconus and Irregular Cornea Contact Lens for Daily Wear is indicated for keratoconus management and for the correction of refractive ametropia (myopia and hyperopia) in aphakic and non-aphakic persons that may exhibit refractive and/or corneal astigmatism, or post-refractive surgery corneal irregularity such as irregular astigmatism up to 2.00 D that does not interfere with visual acuity. The lens may be disinfected with a chemical disinfection system.

Device Name: Eni-Eye SH Soft K Toric Semi Scleral (Efrofilcon A) Soft (hydrophilic) Keratoconus and Irregular Cornea Contact Lens for Daily Wear

Indications for Use: Eni-Eye SH Soft K Toric Semi Scleral (Efrofilcon A) Soft (hydrophilic) Keratoconus and Irregular Cornea Contact Lens for Daily Wear is indicated for keratoconus management and for the correction of refractive ametropia (myopia and hyperopia) in aphakic and non-aphakic persons that may exhibit refractive and/or corneal astigmatism, or post-refractive surgery corneal irregularity such as irregular astigmatism up to 5.00 D that does not interfere with visual acuity. The lens may be disinfected with a chemical disinfection system.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

James P. Bertram -S
2013.03.18 13:37:14 -04'00'

(Division Sign-Off)
Division of Ophthalmic and Ear, Nose and Throat Devices

510(k) Number___K122220_____