



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

Mr. Alan J. Frazer
Director Quality Assurance
UNILENS Corporation, USA
10431 72nd Street North
Largo, FL 33777

APR 20 2011

Re: K110452 – Bundled Special 510 (k) for Parametric Release from Moist Heat Sterilization for Soft (hydrophilic) daily wear contact lenses cleared under P820005, P850002, P880101, P880102, K940777, K941836, K942372, K942494, K960926, K961428, K965012, K971647, K000529, K002408, K041608, K050743, K082393, K100456

Trade/Device Name: Soft Hydrophilic Contact Lenses for Daily Wear
Regulation Number: 21 CFR 886.5925
Regulation Name: Soft (hydrophilic) contact lenses
Regulatory Class: Class II
Product Code: LPL
Dated: March 23, 2011
Received: March 25, 2011

Dear Mr. Frazer:

We have reviewed your Special 510(k) premarket notification of intent to market the device referenced above which requests conversion to parametric release from moist heat sterilization of referenced hydrophilic contact lenses of 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.

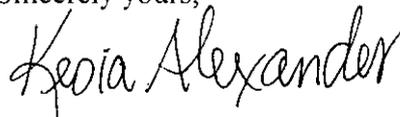
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

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" (21 CFR 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,



Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological 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): K110452

Device Name: See Attached

Indications for Use:

For parametric release from Moist Heat Sterilization of Hydrophilic Contact Lenses

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



(Division Sign-Off)

Division of Ophthalmic, Neurological and Ear,
Nose and Throat Devices

510(k) Number K110452

Status	Trade Names	Approval Number	Cleared Date	Common Name	Device Class	Panel	Product Code
510(k)	Sof-Form II	P820005	06/01/82	Daily Wear Soft (hydrophilic) Contact Lens	II	Ophthalmic	LPL
510(k)	Unilens, Unisite, Simulvue	P850002	02/28/86	Daily Wear Soft (hydrophilic) Contact Lens	II	Ophthalmic	LPL
510(k)	Aquaflex	P880101	2/10/89	Daily Wear Soft (hydrophilic) Contact Lens	II	Ophthalmic	LPL
510(k)	LL-38	P880102	08/11/89	Daily Wear Soft (hydrophilic) Contact Lens	II	Ophthalmic	LPL
510(k)	BayVue Aquaflex MTO	K940777	4/12/1994	Daily Wear Soft (hydrophilic) Contact Lens	II	Ophthalmic	LPL
510(k)	Unilens 38, Unisoft	K941836	07/07/94	Daily Wear Soft (hydrophilic) Contact Lens	II	Ophthalmic	LPL
510(k)	Simulvue 38 LLBI 2	K942372	07/07/94	Daily Wear Soft (hydrophilic) Contact Lens	II	Ophthalmic	LPL
510(k)	Xtra, 4Vue	K942494	09/08/94	Daily Wear Soft (hydrophilic) Contact Lens	II	Ophthalmic	LPL
510(k)	SoftSITE, EMA	K960926	04/10/96	Daily Wear Soft (hydrophilic) Contact Lens	II	Ophthalmic	LPL
510(k)	Soft-55 DW	K961428	05/21/96	Daily Wear Soft (hydrophilic) Contact Lens	II	Ophthalmic	LPL
510(k)	MV2	K965012	03/11/97	Daily Wear Soft (hydrophilic) Contact Lens	II	Ophthalmic	LPL
510(k)	LL Bifocal	K971647	07/15/97	Daily Wear Soft (hydrophilic) Contact Lens	II	Ophthalmic	LPL
510(k)	MVt Toric Bifocal	K000529	02/16/00	Daily Wear Soft (hydrophilic) Contact Lens	II	Ophthalmic	LPL
510(k)	C-VUE 55	K002408	10/17/00	Daily Wear Soft (hydrophilic) Contact Lens	II	Ophthalmic	LPL
510(k)	C-VUE 55 Toric Multifocal	K041608	07/07/04	Daily Wear Soft (hydrophilic) Contact Lens	II	Ophthalmic	LPL
510(k)	Aquaflex 2	K050743	4/13/2005	Daily Wear Soft (hydrophilic) Contact Lens	II	Ophthalmic	LPL
510(k)	C-VUE Advanced	K082393	9/11/2008	Daily Wear Soft (hydrophilic) Contact Lens	II	Ophthalmic	LPL
510(k)	C-VUE Advanced Definitive C-VUE Advanced HydraVUE	K100456	10/28/2010	Daily Wear Soft (hydrophilic) Contact Lens	II	Ophthalmic	LPL