K003170

DEC 15 2000

0. Applicant's Name and Address

ESSILOR International
Contact Lens Division
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Contact Person

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1. Identification of Device

Common Name:	Soft Contact Lens
Trade Name:	RYTHMIC® and RYTHMIC®UV
Classification:	Daily Wear Soft (hydrophilic) Contact Lens
Device classification:	Class II (21 CFR 886.5925 (b) (1))

2. Description of Device

The RYTHMIC® Soft (Spherical, Toric, Multifocal) Hydrophilic Contact Lenses are available as clear or with handling tint color additive (Reactive Blue n°19, 21 CFR 73.3127) and with ultraviolet absorbing additive (benzophenone based):

- in the power range of –20.00 to +10.00 diopters for sphere,
  -0.25 to –6.00 diopters for cylinder
  +0.25 to +3.00 diopters for addition
- with center thickness from 0.09mm – 0.60mm
- with base curves of 8.00mm to 9.20mm
- with diameter of 12.00mm to 15.00mm

The lens material is a hydrophilic random copolymer of N-vinyl-pyrrolidone (NVP), Methyl methacrylate (MMA), Allyl methacrylate (AMA) and AIBN (Azo-iso-butyronitrile) as an initiator. It consists of 73% of water content and 27% of copolymer when immersed in a saline solution. The material may contain an UV absorbing additive (benzophenone based) and a color additive to provide a blue handling tint (Reactive Blue n°19).

This lens material is substantial equivalent to PRECISION UV™ (surfilcon A) described in submission K982988 as: "Random copolymer of N-vinyl-pyrrolidone (NVP), Methyl methacrylate (MMA), Allyl methacrylate (AMA), Ultraviolet absorbing monomer (UVAM) and AIBN (Azo-iso-butyronitrile) as an initiator. It consists of 74% water and 26% surfilcon A"

3. Intended Use

The Essilor RYTHMIC®and RYTHMIC®UV (surfilcon A) Soft (Spherical, Toric, Multifocal) Hydrophilic Contact Lenses are indicated for daily wear. The eye care practitioner may prescribe the contact lens for frequent

replacement wear, with cleaning, disinfection and schedules replacement. The contact lens may be disinfected using a chemical or hydrogen peroxide disinfecting system.

RYTHMIC® spherical lenses are indicated for the correction of visual acuity in not-aphakic persons with non-diseased eyes that are myopic or hyperopic. The lens may be worn by persons who exhibit refractive astigmatism of 1.00 diopters or less that does not interfere with visual acuity.

RYTHMIC® toric lenses are indicated for the correction of visual acuity in not-aphakic persons with non-diseased eyes that are myopic or hyperopic and have refractive astigmatism not exceeding 6 diopters.

RYTHMIC® multifocal lenses are indicated for the correction of visual acuity vision in not-aphakic persons with non-diseased eyes that are presbyopic, with or without associated ametropia. The lens may be worn by persons who require up to +3.00 diopters of addition and who exhibit refractive astigmatism of 0.75 diopters or less that does not interfere with visual acuity.

The RYTHMIC®UV Spherical, Toric and Multifocal Contact Lenses help protect against transmission of harmful UV radiation to the cornea and into the eye.

4. PREDICATE DEVICES

The predicate lenses were selected to address both intended use, design (daily wear spherical, toric and multifocal) and material type (FDA Group II: high water, non ionic polymer) specifically surfilcon A:

- Material: PRECISION UV™ (vasurfilcon A) Hydrophilic Contact Lenses, FDA Group II, high water content, nonionic soft contact lenses for daily wear marketed internationally by WESLEY JESSEN Corporation under PMA P940013 and K982988.

- Multifocal Design: Additions™ (methafilcon A) Hydrophilic Contact Lenses, FDA Group IV, high water content, ionic soft contact lenses for daily wear marketed internationally by SUNSOFT Corporation under PMA 850077 supplement 24 and 510K number K964696.

- Toric Design: Multiples® (methafilcon A) Hydrophilic Contact Lenses, FDA Group IV, high water content, ionic soft contact lenses for daily wear marketed internationally by SUNSOFT Corporation under PMA 850077 supplement 23 and 510K number K964696.

5. CHARACTERISTICS

The characteristics of the RYTHMIC® UV and non UV are compared to the characteristics of the predicate device in the following table.

TABLE 1

Material comparison				
	Predicate device **PRECISION UV™**		Subject device **RYTHMIC® UV Spherical**	
PRODUCTION METHOD	Cast molded process		Cast molded process	
INTENDED USE	Daily wear Correction of ametropia		Daily wear Correction of ametropia	
MATERIAL	vasurfilcon A		surfilcon A	
Type	Group II		Group II	
Color additive	Green D&C Green n°6 CI 69825		Blue C. I. Reactive Blue n°19 CAS 2580-78-1	
UV additive	Yes		Yes	
Characteristics comparison	*Measured*	*Labeled*	*Measured*	*Labeled*
Water Content % @ 20°C	74	74	73.4	73
Refractive Index @ 20°C	1.377 @ 20°C	1.379 @ 25°C	1.379 @ 20°C	1.379 @ 20°C
Dk, Polarimetric method with edge correction @ 35°C x 10^{-11} (cm^2/sec) (ml O_2/ml x mm Hg)	42.0	38.9	40.0	40.0
Elongation at break, % @ 20°C	130	Not available	160	160
Mechanical strength, Mpa @ 20°C	0.60		0.60	0.50
Light transmittance	Tv, % @ 20°C Illuminant A with a 2° observer (between 380 and 780 nm) 98.38	(between 400 and 800 nm) >97	Tv, % @ 20°C Illuminant A with a 2° observer (between 380 and 780 nm) 94.97	Tv, % @ 20°C Illuminant A with a 2° observer (between 380 and 780 nm) Minimum 93

TABLE 2

Lenses design comparison				
	Predicate spherical device **PRECISION UV™**		Subject spherical device **RYTHMIC® UV Spherical**	
Characteristics comparison, -3.00 D 30 lenses	*Measured*	*Labeled*	*Measured*	*Labeled*
Base Curve, mm	8.43 ± 0.18	8.40	8.58 ± 0.12	8.60
Diameter, mm	14.42 ± 0.33	14.40	14.16 ± 0.15	14.20
Power, D	-3.08 ± 0.18	-3.00	-3.10 ± 0.18	-3.00
	Predicate toric device **Multiples® Toric**		Subject toric device **RYTHMIC® UV Toric**	
Characteristics comparison, 30 lenses	*Measured*	*Labeled*	*Measured*	*Labeled*
Spherical power, D Cylinder power, D Axis, °	-1.23 -2.13 178°	-1.50 -2.50 160°	1.57 -2.54 157°	-1.50 -2.50 160°
	Predicate multifocal device **Additions™ Multifocal**		Subject multifocal device **RYTHMIC® UV Multifocal**	
Characteristics comparison, -1.75 D 30 lenses	*Measured*	*Labeled*	*Measured*	*Labeled*
Power, D	-1.80 ± 0.5	-1.75	-1.59 ± 0.8	-1.75

TABLE 3

Material comparison UV against Clear				
	RYTHMIC® UV Spherical		**RYTHMIC® Spherical**	
MATERIAL				
Type	Group II		Group II	
Color additive	Blue		No	
UV additive	Yes		No	
Characteristics comparison (30 lenses)	*Measured*	*Labeled*	*Measured*	*Labeled*
Water Content % @ 20°C	73.4	73	73.9	73
Refractive Index @ 20°C	1.379		1.379	
Dk, Coulometric method @ 35°C x 10^{-11} (cm^2/sec) (ml O_2/ml x mm Hg)	40.0	40.0	40.0	40.0
Elongation at break, %	160	160	170	160
Mechanical strength, MPa	0.60	0.50	0.45	0.50
Light transmittance Tv (%)	95.00	Minimum 93 %	97	Minimum 98 %

6. NON CLINICAL STUDIES

Included as non-clinical studies are: chemistry, toxicology of lens and package materials, microbiology

- **Chemistry**

Material property data were generated on the RYTHMIC® UV and the PRECISION UV™lenses. The data for both devices reflect properties of Group II lenses. The material properties were substantially equivalent.
The lens care product manufacturers have previously shown compatibility of Group II lenses with their products.
The shelf life stability for RYTHMIC® UV and clear RYTHMIC® is based upon stability protocols included with this notification. The study shows that the package, solution and lense are stable over time.
Studies were conducted to determine the leachable monomers on the subject device and on the predicate device. The levels of residual monomers were substantially equivalent.

- **Toxicology, lenses materials**

In accordance with the May 1994 Guidance Document for Daily Wear contact lenses, toxicology studies have been conducted on the RYTHMIC® UV containing UV blocker and handling tint (worst case scenario). The results are summarized below:

Cytotoxicity Test:
A Cytotoxicity Test has been conducted on the subject device according to the NF EN 30993-5, ISO 10993-5 and USP XXIII standards.
The negative controls and the positive controls performed as anticipated. Under the conditions of the study, the test articles were not cytotoxic.

Acute Systemic Injection Test in the mouse:
An evaluation of the safety of the subject device by systemic injection in the mouse after a single intravenous administration or a single intraperitoneal administration has been conducted according to the ISO 10993-11 (1993-E) and the USP XXIII standards.
No sign of toxicity was observed in mice after intravenous injection of the extract prepared with the subject device with the two extraction conditions.

Ocular Eye Irritation Test in the rabbit:
An evaluation of the ocular irritation of 0.9% NaCl and sweet almond oil extracts of the subject article after a single instillation in the rabbit has been conducted according to ISO 10993-10 (1995-E).
No sign of ocular irritation was observed in the rabbits after instillation of the subject device extract in 0.9% NaCl or sweet almond oil.

Sensitization Test:
An evaluation by injection and topical application of the potential to elicit contact dermal allergenicity in the guinea pig of the subject device has been conducted according to ISO 10993-10 (1995 – E) and ASTM F 720-81 (1993) standards.
The sensitization test on the guinea pig performed according to a procedure adapted from ISO 10993-10 – 1195(E) and ASTM F 720-81 (1993) showed that the subject device evaluated as extracts was not sensitizing by topical and intracutaneous route.

- **Toxicology, package materials**

In accordance with the May 1994 Guidance Document for Daily Wear contact lenses, toxicology studies have been conducted on the package materials. The results are summarized below:

Cytotoxicity Test:
A Cytotoxicity Test has been conducted on the primary packaging of the subject device according USP XXIV requirements. The negative controls and the positive controls performed as anticipated. Under the conditions of the study, the test articles were not cytotoxic.

Acute Systemic Injection Test in the mouse :
An evaluation of the safety of the primary packaging of the subject device by systemic injection in the mouse after a single intravenous administration or a single intraperitoneal administration has been conducted according to USP XXIV requirements.
No sign of toxicity was observed in mice after intravenous and intraperitoneal injection of the test article extracts with the two extraction conditions.

Ocular Eye Irritation Test in the rabbit :
An ocular irritation test on the primary packaging was performed in order to determine the risk of ocular irritation after instillation of the test article extract ino.9% NaCL. This study was conducted according to the requirements of ISO 10993-10 (1995-E).
No sign of ocular irritation was observed in the rabbits after instillation of the 0.9% NaCl extract in 3 rabbits.

- **Microbiology**

The lens sterilization process, moist heat sterilization, has been validated to deliver a minimum SAL of 10^{-6}. The lens care product manufacturers have established a reasonable assurance of disinfection efficacy of their care products with lens groups for which they are approved. There is shelf-life stability data that support lens sterility throughout the shelf-life claimed for the product.

7. CLINICAL DATA

It was determined that Clinical Studies were not necessary to establish the safety and efficacy of the lens material surfilcon A. This determination was based on the following:

- The Rythmic®UV lenses were proven to be substantial equivalent to the predicate vasurfilcon A lenses: Precision™ UV from Wesley Jessen. Showed substantial equivalence in physiochemical characteristics.
- The Rythmic® Toric optical design was proven to be equivalent to the predicate toric lenses: Multiples™ Toric from Sunsoft Corporation.
- The Rythmic® Multifocal optical design was proven to be equivalent to the predicate multifocal lenses: Additions™ from Sunsoft Corporation.
- The use of C.I. Reactive Blue 19 is in accordance with color additive listing provisions of 21 Code of Federal Regulations 73.3127

8. CONCLUSIONS DRAWN FROM STUDIES

Validity of Scientific Data:
A contract laboratory using Good Laboratory Practices conducted the Toxicology and Microbiology studies. Chemistry, shelf-life stability and leachables studies were conducted by in-house laboratories and followed ISO standards.
Substantial Equivalence:
The information provided in this 510K establishes that the ESSILOR Rythmic® and Rythmic® UV (surfilcon A) Soft (Hydrophilic) Spherical, Toric and Multifocal Contact Lenses are equivalent in optical, chemical and physical properties of the predicate devices and do not raise any questions of safety and effectiveness. There for the device is substantially equivalent to the predicate device.
Risk and Benefits:
The risks of the subject device are the same as those normally attributed to the wearing of soft (hydrophilic) contact lenses on a daily wear base. The benefits to the patient are the same as those for other soft (hydrophilic) contact lenses.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 15 2000

Ms. Christine Moench
US Regulatory Affairs Senior Manager
Essilor International Contact Lens Division
Clifton House
Brunel Way
Segensworth East, Fareham
Hampshire PO 15 5TX
United Kingdom

Re: K003170
Trade Name: RYTHMIC[R] UV MULTIFOCAL, TORIC and SPHERICAL (surfilcon A) Soft (hydrophilic) Contact Lens for Daily Wear (cast-molded and tinted with C.I. Reactive Blue #19)
Regulatory Class: II
Product Code: 86 LPL
Dated: October 3, 2000
Received: October 10, 2000

Dear Ms. Moench:

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) 594-6413. 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" (21CFR 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/dsma/dsmamain.html".

Sincerely yours,

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

INDICATION FOR USE STATEMENT

510(k) Number (if known) K003170

Device Name:

Indications for Use:

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The RYTHMIC®UV Spherical, Toric and Multifocal Contact Lenses help protect against transmission of harmful UV radiation to the cornea and into the eye.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-the –counter-use_____

Eric C PhD

(Division Sign-off)
Division of Ophthalmic Devices

510(k) Number K003170