



January 03, 2024

HOYA Lamphun Ltd.  
Timothy Ting  
Global QA/RA Director  
Northern Region Industrial Estate, 75/2 Moo 4, Tambol Banklang,  
Amphur Muang, Lamphun 51000 Thailand

Re: K223397

Trade/Device Name: HOYA Illumina (sorafilcon A) Daily Disposable Soft Contact Lens,  
HOYA Illumina (sorafilcon A) Toric Daily Disposable Soft Contact Lens,  
HOYA Illumina (sorafilcon A) Multifocal Daily Disposable Soft Contact Lens.

Regulation Number: 21 CFR 886.5925  
Regulation Name: Soft (Hydrophilic) Contact Lens  
Regulatory Class: Class II  
Product Code: LPL, MVN  
Dated: December 2, 2023  
Received: December 5, 2023

Dear Timothy Ting:

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 (the 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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm> identifies combination product submissions. 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (<https://www.fda.gov/media/99812/download>) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (<https://www.fda.gov/media/99785/download>).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see <https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products>); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems>.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (<https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance>) and CDRH Learn (<https://www.fda.gov/training-and-continuing-education/cdrh-learn>).

Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (<https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice>) for more information or contact DICE by email ([DICE@fda.hhs.gov](mailto:DICE@fda.hhs.gov)) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

**J Angelo Green -S**

J. Angelo Green, Ph.D.

Assistant Director

DHT1A: Division of Ophthalmic Devices

OHT1: Office of Ophthalmic, Anesthesia,

Respiratory, ENT and Dental Devices

Office of Product Evaluation and Quality

Center for Devices and Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known)  
K223397

### Device Name

HOYA Illumina (sorafilcon A) Daily Disposable Soft Contact Lens  
HOYA Illumina (sorafilcon A) Toric Daily Disposable Soft Contact Lens  
HOYA Illumina (sorafilcon A) Multifocal Daily Disposable Soft Contact Lens

### Indications for Use (Describe)

The HOYA Illumina (sorafilcon A) Daily Disposable Soft Contact Lens is indicated for the correction of refractive ametropia (myopia or hyperopia) in non-aphakic person with non-diseased eyes in spherical powers ranging from +5.00D to -12.00D, exhibiting astigmatism of 1.00 diopter or less that does not interfere with visual acuity.

The HOYA Illumina (sorafilcon A) Toric Daily Disposable Soft Contact Lens is indicated for the correction of refractive ametropia (myopia, hyperopia and astigmatism) in non-aphakic person with non-diseased eyes in spherical powers ranging from +5.00D to -10.00D. The lenses may be worn by persons who exhibit astigmatism of up to 2.75 diopters that does not interfere with visual acuity.

The HOYA Illumina (sorafilcon A) Multifocal Daily Disposable Soft Contact Lens is indicated for the correction of refractive ametropia (myopia or hyperopia) and presbyopia in non-aphakic person with non-diseased eyes in spherical powers ranging from +5.00D to -10.00D with add power ranging from +0.50D to +2.50D. The lenses may be worn by persons who exhibit astigmatism of 1.00 diopter or less that does not interfere with visual acuity.

The sorafilcon A contact lenses are to be prescribed for single-use disposable wear and are to be discarded upon each removal.

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

### CONTINUE ON A SEPARATE PAGE IF NEEDED.


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	HOYA Lamphun Ltd. Traditional 510(k) Premarket Notification HOYA Illumina (sorafilcon A) Daily Disposable Soft Contact Lens	Submission Date: 02-December-2023
		Submission No.: K223397

## 510(k) Summary K223397

### SUBMITTER INFORMATION

Date Prepared: November 10, 2022

Name: HOYA Lamphun Ltd.

Address: Northern Region Industrial Estate, 75/2 Moo 4, Tambol Banklang, Amphur Muang,  
Lamphun 51000 Thailand.

Contact Person: Timothy Ting

Global Quality Assurance/Regulatory Affairs Director

Phone Number: (66) 93-132-1699

Email: [chongchai.ting@hoya.com](mailto:chongchai.ting@hoya.com)

### DEVICE INFORMATION

Trade Name: HOYA Illumina (sorafilcon A) Daily Disposable Soft Contact Lens

HOYA Illumina (sorafilcon A) Toric Daily Disposable Soft Contact Lens

HOYA Illumina (sorafilcon A) Multifocal Daily Disposable Soft Contact Lens

Brand Name: ILLUMINA 1 DAY Soft silicone hydrogel contact lens

ILLUMINA 1 DAY Toric Soft silicone hydrogel contact lens

ILLUMINA 1 DAY Multifocal Soft silicone hydrogel contact lens

Common Name: Soft contact lens, daily disposable wear.

Device Classification: Class II (21 CFR 886.5925)

Classification Name: Soft (hydrophilic) contact lens

Product Code: LPL, MVN.

Classification Panel: Ophthalmic.

### PREDICATE DEVICES

HOYA Illumina (sorafilcon A) Daily Disposable Soft Contact Lens is substantially equivalent to the following predicate devices:

#### Primary predicate devices

MyDay<sup>®</sup> (stenfilcon A) ASPHERE Soft Contact Lens,

MyDay<sup>®</sup> (stenfilcon A) TORIC Soft Contact Lens, and


MyDay<sup>®</sup> (stenfilcon A) MULTIFOCAL Soft Contact Lens.

Cleared under K191763.

#### Secondary predicate devices

Bausch + Lomb<sup>®</sup> (samfilcon A) Soft (hydrophilic) Contact Lens

Bausch + Lomb<sup>®</sup> (samfilcon A) Soft (hydrophilic) Contact Lens for Astigmatism

	HOYA Lamphun Ltd. Traditional 510(k) Premarket Notification HOYA Illumina (sorafilcon A) Daily Disposable Soft Contact Lens	Submission Date: 02-December-2023
		Submission No.: K223397

Bausch + Lomb® (samfilcon A) Soft (hydrophilic) Contact Lens for Presbyopia  
Cleared under K131208.

## DEVICE DESCRIPTION

The HOYA sorafilcon A material is made from a hydrophilic siloxane copolymer of N-vinyl pyrrolidone and is 48% water by weight when immersed in a sterile phosphate buffered saline packaging solution. A UV-absorbing monomer is used to block UV radiation. The transmittance characteristics are less than 5% in the UVB range of 280 nm to 315 nm and less than 50% in the UVA range of 316 nm to 380 nm.

The HOYA sorafilcon A Contact Lens is to be prescribed for single-use disposable wear.

The physical properties of the lens are:

Refractive Index	1.408
Light Transmittance	≥ 95%
Water Content	48%
Specific Gravity	1.123
Surface Character	Hydrophilic
Oxygen Permeability	112 x 10 <sup>-11</sup> (cm <sup>2</sup> /sec)(cm <sup>3</sup> O <sub>2</sub> )/(mL x mmHg) @ 35 °C (polarographic method).

The lenses will be manufactured with the following parameters:

Diameter	14.0 mm to 14.7 mm
Center Thickness	0.062 mm to 0.330 mm
Base Curve	8.40 mm to 9.20 mm
Power Range	+5.00D to -12.00D
Cylinder Power (Toric)	-0.75D to -2.75D
Cylinder Axis	0° to 180° in 10° increments
Add Power Range	+0.50D to +2.50D


## INDICATIONS FOR USE

### HOYA Illumina (sorafilcon A) Daily Disposable Soft Contact Lens

The HOYA Illumina (sorafilcon A) Daily Disposable Soft Contact Lens is indicated for the correction of refractive ametropia (myopia or hyperopia) in non-aphakic person with non-diseased eyes in spherical powers ranging from +5.00D to -12.00D, exhibiting astigmatism of 1.00 diopter or less that does not interfere with visual acuity.

### HOYA Illumina (sorafilcon A) Toric Daily Disposable Soft Contact Lens

The HOYA Illumina (sorafilcon A) Toric Daily Disposable Soft Contact Lens is indicated for the correction of refractive ametropia (myopia, hyperopia and astigmatism) in non-aphakic person with non-

	HOYA Lamphun Ltd. Traditional 510(k) Premarket Notification HOYA Illumina (sorafilcon A) Daily Disposable Soft Contact Lens	Submission Date: 02-December-2023
		Submission No.: K223397

diseased eyes in spherical powers ranging from +5.00D to -10.00D. The lenses may be worn by persons who exhibit astigmatism of up to 2.75 diopters that does not interfere with visual acuity.

### HOYA Illumina (sorafilcon A) Multifocal Daily Disposable Soft Contact Lens


The HOYA Illumina (sorafilcon A) Multifocal Daily Disposable Soft Contact Lens is indicated for the correction of refractive ametropia (myopia or hyperopia) and presbyopia in non-aphakic person with non-diseased eyes in spherical powers ranging from +5.00D to -10.00D with add power ranging from +0.50D to +2.50D. The lenses may be worn by persons who exhibit astigmatism of 1.00 diopter or less that does not interfere with visual acuity.

The sorafilcon A contact lenses are to be prescribed for single-use disposable wear and are to be discarded upon each removal.

### COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICES

A side-by-side comparison of technological characteristics of the predicate devices and the new device:

Property	Primary Predicate Device MyDay <sup>®</sup> (stenfilcon A) Soft Daily Disposable Contact Lens Product Family K191763	Secondary Predicate Device Bausch + Lomb (samfilcon A) Soft (hydrophilic) Contact Lens Product Family K131208	Subject Device HOYA Illumina (sorafilcon A) Daily Disposable Soft Contact Lens Product Family
Intended Use	Daily wear and daily disposable cornea soft contact lens for myopia, hyperopia, astigmatism, presbyopia	Daily wear and daily disposable cornea soft contact lens for myopia, hyperopia, astigmatism, presbyopia	Same as predicate devices
Functionality	The contact lenses act as a refractive medium that focus light rays from near and distant objects on the retina.	The contact lenses act as a refractive medium that focus light rays from near and distant objects on the retina.	Same as predicate devices
Modality	Daily disposable wear contact lens	Daily disposable wear contact lens	Same as predicate devices
Manufacturing Method	Cast Molded	Cast Molded	Same as predicate devices
Material Group	Silicone Hydrogel FDA Group II (high water content, nonionic polymer)	Silicone Hydrogel FDA Group I (low water content, nonionic polymer)	Silicone Hydrogel FDA Group I (low water content, nonionic polymer)
FDA Category (Group)			
USAN Name	stenfilcon A	samfilcon A	sorafilcon A
Water Content	54%	46%	48%
Oxygen Permeability*	80	114	112
Refractive Index	1.401	1.411	1.408

	HOYA Lamphun Ltd. Traditional 510(k) Premarket Notification HOYA Illumina (sorafilcon A) Daily Disposable Soft Contact Lens	Submission Date: 02-December-2023
		Submission No.: K223397

Property	Primary Predicate Device MyDay® (stenfilcon A) Soft Daily Disposable Contact Lens Product Family K191763	Secondary Predicate Device Bausch + Lomb (samfilcon A) Soft (hydrophilic) Contact Lens Product Family K131208	Subject Device HOYA Illumina (sorafilcon A) Daily Disposable Soft Contact Lens Product Family
Specific Gravity	1.033	1.048	1.123
Visibility Tint	Reactive Blue 246	Reactive Blue 246	No color pigment was added
Sterilization Method	Moist Heat	Autoclave	Same as predicate devices

Note: \*Oxygen Permeability shown was determine by polarographic method:  
 $\times 10^{-11} [(cm^2/sec) \times (cm^3O_2) / (ml \times mmHg)] @ 35 ^\circ C$

### SUMMARY OF NON-CLINICAL TESTING

Non-clinical studies for HOYA sorafilcon A Contact Lenses were conducted in accordance with FDA’s Class II Daily Wear Contact Lenses - Premarket Notification [510(k)] Guidance Document issued date June 27, 1994 and 21 CFR Part 58 Good Laboratory Practice for Nonclinical Laboratory Studies. Each test was conducted based on the ANSI, ISO, and ASTM standard as indicated below:


- Lens shape, edge thickness, inclusion and surface imperfection per ANSI Z80.20:2016 and ISO 18369-3:2017.
- Lens parameters per ANSI Z80.20: 2016 and ISO 18369-3:2017.
- Water content per ANSI Z80.20-2016 and ISO 18369-4:2017.
- Refractive index per ANSI Z80.20-2016 and ISO 18369-4:2017.
- Light transmittance per ANSI Z80.20-2016 and ISO 18369-4:2017.
- UV radiation transmittance per ANSI Z80.20-2016 and ISO 18369-4:2017.
- Extractables per ANSI Z80.20-2016 and ISO 18369-4:2017.
- Contact angle per ANSI Z80.20-2016.
- Mechanical properties per ANSI Z80.20-2016 and ASTM D1708-02a.
- Sterile blister packaging integrity per ASTM 1929-98.

All test results met the pre-established acceptance criteria which demonstrated the lenses are safe and effective.

### SUMMARY OF BIOCOMPATIBILITY TESTING

Biocompatibility testing for HOYA sorafilcon A Contact Lenses was conducted on in accordance with the FDA’s Class II Daily Wear Contact Lenses - Premarket Notification [510(k)] Guidance Document issued date June 27, 1994, ISO 10993-1:2018 Biological Evaluation of Medical Devices and 21 CFR Part 58 Good Laboratory Practice for Nonclinical Laboratory Studies as listed below:

- Cytotoxicity per ISO 10993-5: 2009

	HOYA Lamphun Ltd. Traditional 510(k) Premarket Notification HOYA Illumina (sorafilcon A) Daily Disposable Soft Contact Lens	Submission Date: 02-December-2023
		Submission No.: K223397

- Sensitization per ISO 10993-10: 2021
- 22 day contact lens wear study in rabbits per ISO 9394: 2012
- Acute Ocular Irritation per ISO 10993-23:2021
- Systemic Toxicity per ISO 10993-11: 2017
- Genotoxicity (bacterial reverse mutation and chromosomal aberration assays studies) per ISO 10993-3: 2014
- Chemical characterization of lens materials per ISO 10993-18: 2020

The biological compatibility testing was conducted on the subject device phosphate buffered saline packaging solution as listed below:

- Cytotoxicity per ISO 10993-5: 2009
- Sensitization per ISO 10993-10: 2021
- Acute Ocular Irritation per ISO 10993-23:2021

The biological compatibility testing was also conducted on the subject device final packaging materials as listed below:


- Cytotoxicity per ISO 10993-5: 2009
- Acute systemic toxicity per ISO 10993-11:2017
- Acute Ocular Irritation per ISO 10993-23:2021

HOYA Illumina (sorafilcon A) Daily Disposable Soft Contact Lens was demonstrated to be biocompatible with the mucosal membrane (cornea) and the device performs as expected and is equivalent to the predicates without creating additional risk to the user.

## SUMMARY OF CLINICAL PERFORMANCE DATA

HOYA conducted a three-month, double-masked (subject and investigator), bilateral, randomized, multicenter (9 centers) clinical trial was conducted in USA and UK with a total of 133 subjects enrolled. Eighty subjects completed the study as per protocol: 59 subjects wearing test lenses and 21 subjects wearing control lenses. No serious or significant ocular adverse events were reported.

The primary safety endpoint was HOYA sorafilcon A daily disposable contact lens was non-inferior to the control lens with respect to the percentage of eyes with ocular adverse events across all follow-up visits using a non-inferiority margin of 5%. No serious or significant ocular adverse events were reported. There were 20 reported adverse events in 17 subjects. Five of these were ocular adverse events in four subjects, all of which were classified as non-significant. Two of the ocular adverse events were considered lens-related: bilateral redness. The low incidence of ocular adverse events ensured that both of the primary safety hypotheses were met.

	HOYA Lamphun Ltd. Traditional 510(k) Premarket Notification HOYA Illumina (sorafilcon A) Daily Disposable Soft Contact Lens	Submission Date: 02-December-2023
		Submission No.: K223397

The primary efficacy hypotheses related to visual acuity (VA). The proportion of eyes with VA with contact lenses and best sphere-correction corrected to 1.0 (0.0 logMAR, 20/20) or better was calculated at each visit. With VA calculated to the nearest line, the proportions ranged from 94% to 99% for the test lens and 94% to 100% for the control lens. Using this criterion, both lenses achieved the target threshold of 90% at each visit. With VA calculated to the nearest letter, these proportions ranged from 83% to 93% for the test lens and 83% to 91% for the control lens. It is notable, however, that with habitual lenses, the proportion was also below the target threshold of 90%: 77% of test eyes and 91% of control eyes. The mean sphere-corrected VAs at follow-up (13 weeks) were 0.07 and -0.06 logMAR for the test and control lenses respectively. At each visit, the upper and lower limit values of the 95% confidence intervals were better than 0.0 logMAR (1.0 decimal, 20/20) and, therefore, a primary efficacy hypothesis was met.

The results of the study demonstrated that HOYA Illumina (sorafilcon A) Soft Contact Lens is safe and has effectiveness substantially equivalent to the predicate device, MyDay® (stenfilcon A) Soft Daily Disposable Contact Lens.

#### **SUBSTANTIAL EQUIVALENCE CONCLUSION**

The cumulative results of the bench performance testing, *in vitro* and *in vivo* testing, biocompatibility testing, and clinical study sponsored by HOYA Lamphun Ltd. demonstrated that the safety, effectiveness, and performance of the subject device is substantially equivalent to the predicate devices.