July 7, 2026

HOYA Lamphun , Ltd.
Timothy Ting
Vice President of Quality Assurance/Regulatory Affairs
Northern Region Industrial Estate, 75/2 Moo 4
Tambol Banklang, Amphur Muang
Lamphun, 51000
Thailand

Re: K261812
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: May 27, 2026
Received: June 8, 2026

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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) 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

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K261812

Please provide the device trade name(s).

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

Please provide your Indications for Use below.

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.

Please select the types of uses (select one or both, as applicable).	☒ Prescription Use (21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)
Please select the age group(s) for which the device(s) is to be used.	☐ Neonates/Newborns (Birth to < 29 days old) ☐ Infants (29 days old to < 2 years old) ☐ Children (2 years old to < 12 years old) ☒ Adolescents (12 years old to < 22 years old) ☒ Adults (22 years old and greater)

510(k) Summary
K261812

SUBMITTER INFORMATION

Date Prepared: May 27, 2026
Name: HOYA Lamphun Ltd.
Address: Northern Region Industrial Estate, 75/2 Moo 4, Tambol Banklang, Amphur Muang, Lamphun 51000 Thailand.
Contact Person: Timothy Ting
Vice President of Quality Assurance/Regulatory Affairs
Phone Number: (66) 93-132-1699
Email: 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: Lens, Contact, (Disposable)
Product Code: LPL, MVN.
Classification Panel: Ophthalmic.

PREDICATE DEVICES

HOYA Illumina (sorafilcon A) Daily Disposable Soft Contact Lens with Reactive Blue 246 as visibility handling tint is substantially equivalent to the following predicate devices cleared under K223397:

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

DEVICE DESCRIPTION

The HOYA Illumina (sorafilcon A) Daily Disposable Soft Contact Lenses are made from sorafilcon A material, 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. This lens with Reactive Blue 246 dye to provide visibility handling tint. The color additive conforms to 21 CFR Part 73.3106.

The HOYA Illumina (sorafilcon A) Daily Disposable Soft Contact Lenses are 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	1.131
Surface Character	Hydrophilic
Oxygen Permeability	112 x 10^{-11} (cm^2/sec)(cm^3O_2)/(mL x mmHg) @ 35 ^{0}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	0^0 to 180^0 in 10^0 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-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 Lenses are 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 HOYA Illumina (sorafilcon A) Daily Disposable Soft 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	**Predicate Device** HOYA Illumina (sorafilcon A) Daily Disposable Soft Contact Lens Product Family K223397	**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	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.	Same as predicate devices
Modality	Daily disposable wear contact lens	Same as predicate devices
Manufacturing Method	Cast Molded	Same as predicate devices
Material Group	Silicone Hydrogel FDA Group I (low water content, nonionic polymer)	Same as predicate devices
USAN Name	sorafilcon A	Same as predicate devices
Water Content	48%	Same as predicate devices
Oxygen Permeability*	112	Same as predicate devices
Refractive Index	1.408	Same as predicate devices
Specific Gravity	1.123	1.131
Visibility Tint	No color pigment was added	Reactive Blue 246
Sterilization Method	Moist Heat	Same as predicate devices

Note: *Oxygen Permeability shown was determined by polarographic method:
x 10^{-11} [(cm^2/sec)x(cm^3O_2)/ (ml x mmHg)] @ 35 ^{0}C

SUMMARY OF NON-CLINICAL TESTING

Non-clinical studies for HOYA Illumina (sorafilcon A) Daily Disposable Soft Contact Lenses with Reactive Blue 246 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 (R2021) 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 (R2021) and ISO 18369-4:2017.
- Contact angle per ANSI Z80.20-2016.
- Mechanical properties per ANSI Z80.20-2016 (R2021) and ASTM D882-18.
- Sterile blister packaging integrity per ASTM F1929-23.

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

SUMMARY OF BIOCOMPATIBILITY TESTING

Biocompatibility testing for HOYA Illumina (sorafilcon A) Daily Disposable Soft Contact Lenses with Reactive Blue 246 was conducted 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
- Guinea Pig Maximization (GPMT) Skin 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

The above studies were conducted using the final finished sterilized subject device lenses as the test article. No separate biocompatibility testing was conducted on the primary packaging or packaging solution, since these two device components are identical (in all materials, formulation, processing, etc.) to the primary packaging and packaging solution used for the K223397 predicate. Please note that while that the 22-day contact lens study in rabbits per ISO 9394:2012 and the GPMT skin sensitization study per ISO 10993-10:2021 were performed, these two studies were not needed to support the substantial equivalence of the subject device lenses, since the only change was the addition of Reactive Blue 246 as a handling tint to the lenses.

HOYA Illumina (sorafilcon A) Daily Disposable Soft Contact Lenses with Reactive Blue 246 were 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.

SUBSTANTIAL EQUIVALENCE CONCLUSION

The cumulative results of the bench performance testing, *in vitro* and *in vivo* testing, and biocompatibility testing on the HOYA Illumina (sorafilcon A) Daily Disposable Soft Contact Lenses with Reactive Blue 246 sponsored by HOYA Lamphun Ltd. demonstrated that the safety, effectiveness, and performance of the subject device is substantially equivalent to the predicate devices.