June 22, 2026

Beyond 700 Pty Ltd
Dr. Burkhardt Schuett
COO
8 Miller Street
Petersham, NSW 2049
Australia

Re: K253176
Trade/Device Name: TearView
Regulation Number: 21 CFR 886.1120
Regulation Name: Ophthalmic Camera
Regulatory Class: Class II
Product Code: HKI
Dated: May 9, 2026
Received: May 11, 2026

Dear Burkhardt Schuett:

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,

Alexander Beylin -S Date: 2026.06.22 14:27:17 -04'00'

for CAPT Bardley Cunningham, MSE, RAC
Acting 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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K253176

Device Name
TearView

Indications for Use *(Describe)*
TearView is an ophthalmic camera that is intended to be used by an eye care specialist in adult patients to take digital images of the eye and surrounding areas.

TearView is a non-contact thermograph that captures and stores images of thermal (emissivity) pattern of the ocular surface including its tear film during blinking.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) SUMMARY

Preparation Date:	5th June 2026
Applicant:	Beyond 700 Pty Ltd Unit 38 9 Hoyle Avenue Castle Hill, NSW, 2154 Australia
Contact Person:	Dr Burkhardt Schuett
Contact Phone	+61 (0) 432 175 797
Device Trade Name:	TearView
Device Version:	Version 3
Common Name:	Ophthalmic Imaging Device
Classification Name:	Camera, Ophthalmic, AC-powered
Device Classification:	Class II
Regulation:	21 CFR 886.1120
Predicate Device:	United Integrated Non-Contact Thermograph System Model IT-85 (**K111771**)
Product Code	HKI

1. Device Description

The device TearView is a thermal camera designed to be used for eye conditions that a medical professional considers to have an affect on the thermal (emissivity) pattern of the eye during eye opening and blinking. As such, it is a thermal camera optimized to make recordings of thermal (emissivity) patterns coming off the open eye including its tear film in the blinking process. It is designed as an accessory to a slit lamp (that needs to be provided by the user). It is attached to the turret of a slit lamp via a provided arm. The slit lamp mechanism is used to focus the device on the eye of the patient whose head is supported in the chin / headrest of the slit lamp.

TearView is powered by a Windows computer/tablet (not part of the device) via an USB cable connection with a maximum theoretical output of 25mWatt (5V at 5mA). It also receives information from and sends information to the computer/tablet via the same cable connection. TearView is based on a 640×480 pixel array microbolometer with a fixed focus lens system and passively acquires and records the thermal radiation emitted from the ocular surface including its tear film and presents this as a grey-scale video. TearView uses its own touch-screen enabled Windows-based software, which needs to be installed on a computer/tablet (provided by the user) to run the device and to store the recordings for review. The thermal imaging is from a distance and completely passive, hence the device has no light source, can run in the dark, and never contacts the patient directly. Such recordings of unforced normal blinks of a subject take less than 30 seconds and can be taken at any temperature between 20-40°C with no other environmental control or specific blinking of the subject necessary.

2. Indications for Use

TearView is an ophthalmic camera that is intended to be used by an eye care specialist in adult patients to take digital images of the eye and surrounding areas.

TearView is a non-contact thermograph that captures and stores images of thermal (emissivity) pattern of the ocular surface including its tear film during blinking.

3. Substantial Equivalence

TearView is similar in principle function to the predicate thermographic camera (see Table 1), however TearView is an improvement on a number of technical parameters that define the effectiveness of this technology. TearView has higher spatial and temperature resolutions as well as a higher frame rate than the predicate device that was previously cleared under K111771. Overall, this is an improvement allowing better and clearer images of the thermal patterns coming from the eye, and as a difference to the Indications for Use statement of the predicate, it was included that the resulting emissivity pattern arise from the ocular surface including the tear film covering the eye as well. Furthermore, TearView is designed as an add-on to a slit lamp and needs an USB connection to an external computer for operation and power-supply rather than being a stand-alone device that is connected to the mains like the predicate. These features do not raise question regarding safety and effectiveness. TearView is not directly connected to the mains, runs on much lower voltage, and does not directly contact the patient.

Table 1: Similarities and differences between the proposed device TearView and the predicate device.

	TearView	**Predicate, UIS Non-Contact Thermograph System Model IT-85**	**Comparison**
510(k) Number	K253176	K111771	
Regulation number	21 CFR 886.1120	21 CFR 886.1120	Identical
Product code	HKI	HKI	Identical
Indications for Use	TearView is an ophthalmic camera that is intended to be used by an eye care specialist in adult patients to take digital images of the eye and surrounding areas. TearView is a non-contact thermograph that captures and stores images of thermal (emissivity) patterns of the ocular surface including its tear film during blinking.	The UIS Non-contact Thermograph system is an ophthalmic imaging device that stores, archives, and manipulates digital images of ocular surface temperature measurements taken by a physician in adult patients.	Nearly identical. Both devices capture and store images of thermal emissivity patterns of the ocular surface. TearView and its software do not allow for manipulation of an image that was taken
Camera Type	Thermograph (Long wave infrared 7.5-13µm)	Thermograph (Long wave infrared 7.5-13µm)	Identical
Camera Resolution	640x480 pixel	320x240 pixel	Not Identical TearView has a higher spatial resolution than the predicate.

Camera frame rate	30 Hz	30 Hz	Identical
Camera sensor noise equivalent temperature (thermal sensitivity)	28mK	70mK	Not identical TearView has a higher thermal sensitivity than the predicate
Recorded media	Digital (external Window-computer or tablet)	Digital (Computer system part of this stand alone device)	Not identical TearView is operated from an external computer
Contact area with patient	none	Head (chin and forehead)	Not identical TearView is used with a third-party slit-lamp and is not in direct contact with the patient
Means for alignment	Fixed focus of the camera, for device alignment a slit-lamp mechanism and head rest of that slit lamp is used	Fixed focus of the camera, there are mechanism to move camera and built in head rest as part of this stand alone device	Similar TearView is designed as an add-on to a slit lamp and used the slit lamps function for alignment and focus
Working distance	40mm	Not known	
Light Source	none	none	Identical
Power Source	USB-C, DC	AC-powered	Not identical

4. Bench Performance and Safety testing

TearView complies to the requirements applicable to ophthalmic instruments (ISO 15004-1: 2020) and the standard for basic and electrical safety (IEC 60601-1:2005 + A1:2012). It complies with the standard IEC 60601-1-2: 2014 Part 1+2, set for active devices with regard to electrostatic discharge immunity, radiated field immunity, magnetic field immunity, and unintended emission. The device has been bench tested for its ability to observe the thermal emissivity patterns of the ocular surface including its tear film across a range of ambient temperatures.

5. Performance Testing

TearView has been field tested in real world use with more than 1,000 ophthalmic patients by 3rd party independent eye care specialists in continuous use for more than 4 years with no adverse events. Some of the resulting real world testing has been published (Coroneo MT et al. High-Resolution Ocular Surface Imaging: Real-Time Visualization of Tear Film Dysfunction. Cornea. 2024 May 30 and Kokkinakis J et al. Effects on the Human Tear Film of Applying Skin Lipids to the Ocular Surface. Cornea. 2023 Dec 1;42:1562-1571). In conclusion, it was shown that TearView enables the dynamic emissivity pattern of ocular surface including its tear film to be captured safely.

6. Conclusion

The basic and underlying function of the ophthalmic camera TearView is the same as for the predicate. Due to its technical improvements compared to the predicate it allows more detailed thermographic imaging of the eye including its tear film during blinking.. Its use for more than 4 years in Australian eye clinics without any adverse events and the bench performance testing demonstrate that it is as safe and effective as the predicate. Taken together, TearView is therefore substantially equivalent to the predicate device.