April 23, 2024

AEYE Health Inc.
% Ahava Stein
Regulatory Consultant
A. Stein - Regulatory Affairs Consulting Ltd.
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Kfar Saba, 4442518
Israel

Re: K240058
Trade/Device Name: Aeye-ds
Regulation Number: 21 CFR 886.1100
Regulation Name: Retinal Diagnostic Software Device
Regulatory Class: Class II
Product Code: PIB
Dated: January 8, 2024
Received: March 15, 2024

Dear Ahava Stein:

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) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Elvin Y. Ng -S

Elvin Ng
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)*
K240058

Device Name
AEYE-DS

Indications for Use *(Describe)*
The AEYE-DS is indicated for use by health care providers to automatically detect more than mild diabetic retinopathy (mtmDR) in adults diagnosed with diabetes who have not been previously diagnosed with diabetic retinopathy. The AEYE-DS is indicated for use with the Topcon NW400 camera and the Optomed Aurora camera.

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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510(K) SUMMARY

AEYE-DS DEVICE

510(k) Number K240058

Applicant Name: AEYE Health Inc.

Contact Person: Zack Dvey-Aharon, Ph.D.

Contact: AEYE Health Inc.
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Date Prepared: April 17, 2024

Trade Name: AEYE-DS

Classification Name: 21 CFR 886.1100; (Product Code PIB)
Retinal Diagnostic Software Device

Classification: Class II

Predicate Device:

The AEYE-DS device is substantially equivalent to the following predicate device:

Device	Manufacturer	510(k) No.
AEYE-DS	AEYE Health Inc.	K221183

Device Description:

AEYE-DS is a retinal diagnostic software device that incorporates an algorithm to evaluate retinal images for diagnostic screening to identify retinal diseases or conditions. Specifically, the AEYE-DS is designed to perform diagnostic screening for the condition of more-than-mild diabetic retinopathy (mtmDR).

The AEYE-DS is comprised of 5 software components: (1) Client; (2) Service; (3) Analytics; (4) Reporting and Archiving; and (5) System Security. The device configuration of these modules is presented in the figure below, indicating which components are local to the user and which are remotely located.

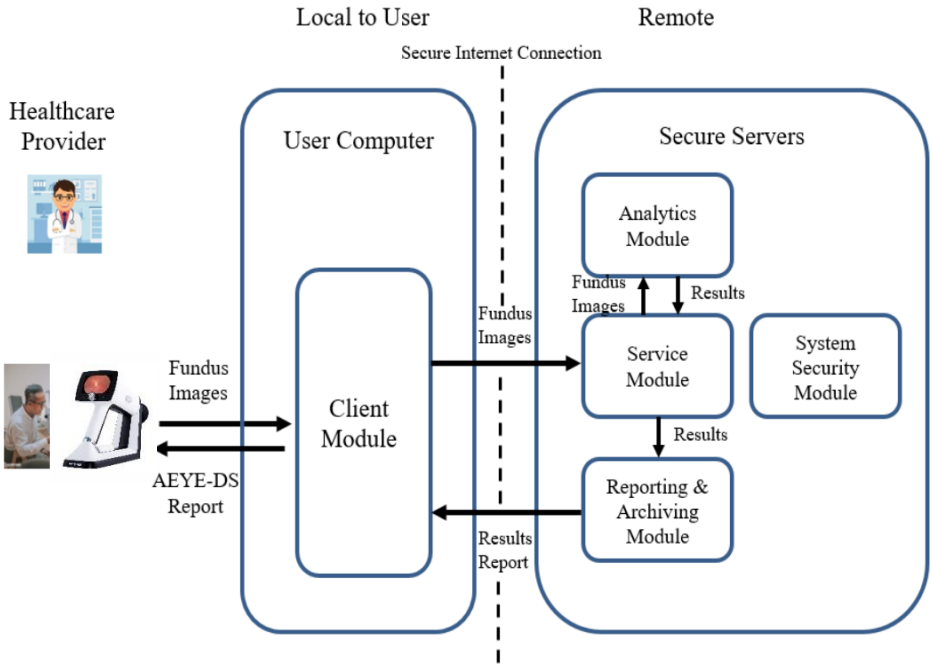

Figure 1: Device Configuration

The AEYE-DS device is based on the main technological principle of Artificial Intelligence (AI) software as a medical device. The software as a medical device uses artificial intelligence technology to analyze specific disease features from fundus retinal images for diagnostic screening of diabetic retinopathy.

The AEYE-DS device is based on the principle of operation, whereby a fundus camera is used to obtain retinal images. The fundus camera is attached to a computer, where the Client module/software is installed. The Client module/software guides the user to acquire the images and enables the user to interact with the server-based analysis software over a secure internet connection. Using the Client module/software, users identify the fundus images per eye to be dispatched to the Service module/software. The Service module/software is installed on a server hosted at a secure datacenter, receives the fundus images and transfers them to the Analytics module/software. The Analytics module/software, which runs alongside the Service module/software, processes the fundus images and returns information on the image quality and the presence or absence of mtmDR to the Service module/software. The Service module/software then returns the results to the Client module/software.

Intended Use/Indication for Use:

The AEYE-DS is indicated for use by health care providers to automatically detect more than mild diabetic retinopathy (mtmDR) in adults diagnosed with diabetes who have not been

previously diagnosed with diabetic retinopathy. The AEYE-DS is indicated for use with the Topcon NW400 camera and the Optomed Aurora camera.

Prescription Use only: Federal law restricts this device for sale by or on the order of a physician.

Performance Standards:

The AEYE-DS device complies with the following FDA recognized consensus standards:

- Software Verification and Validation Testing Software verification and validation testing were conducted, and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices." The software for this device was considered as requiring "Enhanced Documentation", since a failure or latent flaw in the software could result in serious injury to the patient through incorrect or delayed information or through the action of a care provider.
- IEC 62304 Edition 1.1 2015-06 CONSOLIDATED VERSION Medical device software – Software life cycle processes
- ISO 14971 Medical devices – Application of risk management to medical devices

Non-Clinical (Bench) Performance Data:

Software validation testing in compliance with FDA guidelines for software validation and IEC 62304 standard requirements was conducted.

The software hazard analysis was performed as part of the system hazard analysis. The hazards of the software influencing the operations of the system, the hardware problems impairing the software's integrity, and the incorrect operations of the system by the user that could affect the software's correct functioning, were handled as part of the system hazard analysis. The risks and the risk reductions are found in the Risk Analysis for the AEYE-DS device.

The cybersecurity requirements for the AEYE-DS device were identified according to the Content of Premarket Submissions for Management of Cybersecurity in Medical Devices. A threat analysis was performed and documented in the Cybersecurity Report.

The results of the performance tests, including software validation, cybersecurity and hazard analysis demonstrated that the AEYE-DS device is substantially equivalent to the predicate devices.

Animal Performance Data / Histology Data:

Not Applicable

Clinical Performance Data:

The AEYE-DS device performance for automated detection of more than mild Diabetic Retinopathy (mtmDR) from digital funduscopic images was demonstrated in several clinical studies. Both studies were prospective, multi-center, single-arm, blinded studies. The studies were conducted at study sites in the United States. The study populations represented the target population for the use of this device and consisted of stable, visually asymptomatic subjects who were previously diagnosed with diabetes and had no prior diagnosis of DR. Subjects participated in a routine retinal screening test for diabetic retinopathy (DR) in hospitals, primary care clinics or medical research centers. Patients of both genders, all ethnicities and ≥22 years of age were recruited to the study. General patient demographics, medical history, concomitant medications, fundoscopy system used, OCT system used, etc., were obtained for each study subject.

Novice operators, who had not previously performed ocular imaging, obtained fundoscopy images from each eye of the patient, using the Optomed Aurora funduscopic camera. Upon submission of the fundoscopy images to the AEYE-DS client software, a diagnostic result (and PDF diagnostics report) of more than mild DR (mtmDR) detected or more than mild DR not detected was produced. A result of 'insufficient quality' was determined if the novice operator reached a maximum of 6 image submission attempts and one or more of the images was still of insufficient image quality. After the novice operator generated an AEYE-DS diagnostic output, each participant underwent additional retinal imaging captured by a professional ophthalmic photographer, to obtain dilated four widefield color fundus images, lens photography for media opacity assessment and macular optical coherence tomography (OCT) imaging. The professional images were sent to an independent reading center where the severity of retinopathy and clinically significant diabetic macular edema (DME) were determined according to the Early Treatment for Diabetic Retinopathy Study severity (ETDRS) scale. The Reading Center diagnostic results formed the reference standard (ground truth) for the study. As part of the final clinical assessment, each participant was categorized as mtmDR+ or mtmDR-, based on the worst of two eyes. The final clinical assessment based on the worst of two eyes was compared with the AEYE- DS output, at the participant level.

In Study 1 a total of 317 subjects were enrolled in the study. The baseline demographic data and characteristics analysis showed that the mean age was 55 years, 51% were male and 49% were female, 26% were African-American, 47% White and 22% Hispanic or Latino, the remainder were of other racial/ethnic origins. Approximately 94% of the subjects in the study were diagnosed with type 2 diabetes while approximately 6% percent were diagnosed with type 1 diabetes. Average duration of diabetes since was 10 years (SD=8). Mean HbA1c level was 8.2% (SD=2.1).

The results of sensitivity and specificity in Study 1 based on images obtained from the handheld Optomed Aurora camera were 92% [CI:79%; 97%] and 94% [CI: 90%; 96%] (fundus and multi-modality based), respectively. The AEYE-DS device successfully identified all participants with ETDRS level 43 or higher. Positive Predictive Value (PPV) was 68% [CI: 54%; 79%] and the

Negative Predictive Value (NPV) was 99% [CI: 96%; 100%]. Further sub-analyses showed that there were no significant effects of age, sex, race/ethnicity, HbA1c, diabetic duration since diagnosis, lens status, positive ETDRS levels, or pharmacological dilation on sensitivity and specificity. 89% of the subjects did not require pharmacologic dilation.

In Study 2 a total of 362 subjects were enrolled in the study. The baseline demographic data and characteristics analysis showed that the mean age was 58 years, 45% were male and 55% were female, 19% were African-American, 46% White and 30% Hispanic or Latino, the remainder were of other racial/ethnic origins. Approximately 97% of the subjects in the study were diagnosed with type 2 diabetes while approximately 3% percent were diagnosed with type 1 diabetes. Average duration of diabetes since was 10 years (SD=8). Mean HbA1c level was 8.3% (SD=2.2).

The results in Study 2 based on images obtained from the handheld Optomed Aurora camera were 93% [CI:80%; 97%] (fundus based) and 90% (CI:77%; 96%) (multi-modality based) for sensitivity and 89% [CI: 85%; 92%] (fundus based) and 89% [CI: 84%; 92%] (multi-modality based) for specificity. The AEYE-DS device successfully identified all participants with ETDRS level 43 or higher. Positive Predictive Value (PPV) was 53% [CI: 41%; 64%] (for both modalities) and the Negative Predictive Value (NPV) was 99% [CI: 97%; 100%] (fundus based) and 98% [CI: 96%; 99%] (multi-modality based). Further sub-analyses showed that there were no significant effects of sex, race/ethnicity, HbA1c, diabetic duration since diagnosis, lens status, positive ETDRS levels, or pharmacological dilation on sensitivity and specificity. The only sub-analyses which showed a significant effect was age, with the lower age group (<55 years) showing better results than the higher age group. 75% of the subjects received an AEYE-DS diagnostic output result on the first submission attempt. 90% of subjects did not require pharmacologic dilation.

PPV in both studies was influenced by the actual prevalence of mtmDR+ patients in the studies diabetic population (i.e., 12%), as these were not enriched studies. Furthermore, the PPV and NPV results obtained in both studies were similar, demonstrating the robustness of the studies.

Key results from the clinical studies are summarized in the table below.

	AEYE-DS Device Fundus-based Analysis		**AEYE-DS Device Multi-modality-based Analysis**	
	AEYE-DS Study 1	**AEYE-DS Study 2**	**AEYE-DS Study 1**	**AEYE-DS Study 2**
Sensitivity	92% [79%; 97%]	93% [80%; 97%]	92% [79%; 97%]	90% [77%; 96%]
Specificity	94% [90%; 96%]	89% [85%; 92%]	94% [90%; 96%]	89% [84%; 92%]

Imageability	99% [98%; 100%]	99% [97%; 100%]	99% [98%; 100%]	99% [97%; 100%]
PPV	68% [54%; 79%]	53% [41%; 64%]	68% [54%; 79%]	53% [41%; 64%]
NPV	99% [96%; 100%]	99% [97%; 100%]	99% [96%; 100%]	98% [96%; 99%]

The imageability results from both Study 1 and Study 2, reflecting data on the usability in the hands of the study novice operators, reported 99% imageability for the AEYE-DS device using the Optomed Aurora fundoscopy camera.

Precision Study

Overall, twenty one (21) participants were included in the final statistical analysis. All 21 participants completed the entire AEYE-DS device imaging protocol and diagnostic output twelve consecutive times, imaged by three different novice operators, using two different Optomed Aurora fundoscopy devices, except for one subject who withdrew consent after 10 image sets (operator #3 did not use camera #2) for a total of 250 image sets/diagnoses in total. Per protocol, operators allowed subjects at least 8 minutes between successive imaging. The results are presented in the following tables.

Precision Tables:

Intra-Operator Repeatability	Repeat 2 - mtmDR		
Repeat 1 - mtmDR	mtmDR +	mtmDR -	Insufficient quality
mtmDR +	58	0	0
mtmDR -	1	66	0
Insufficient quality	0	0	0
OA	99% (124/125) [96%; 100%]		
APA	99% [95%; 100%]		
ANA	99% [96%; 100%]		
AUA	Not presented as all cases were of sufficient quality		

Between – Operator Reproducibility	Operator 3								
Operator 1	mtmDR + Operator 2			mtmDR - Operator 2			Insufficient quality Operator 2		
	mtmDR+	mtmDR-	IQ	mtmDR+	mtmDR-	IQ	mtmDR+	mtmDR-	IQ
mtmDR +	18	2	0	0	0	0	0	0	0
mtmDR -	0	0	0	0	21	0	0	0	0
Insufficient quality	0	0	0	0	0	0	0	0	0
OA	95% (39/41) [84%; 99%]								
APA	97% [88%; 99%]								
ANA	97% [90%; 99%]								
AUA	Not presented as all cases were of sufficient quality								

Between-Device Reproducibility	Device 2 mtmDR		
Device 1 - mtmDR	mtmDR +	mtmDR -	Insufficient quality
mtmDR +	28	1	0
mtmDR -	1	32	0
Insufficient quality	0	0	0
OA	97% (60/62) [89%; 99%]		
APA	97% [88%; 99%]		
ANA	97% [90%; 99%]		
AUA	Not presented as all cases were of sufficient quality		

Human Factors Validation Study

Usability of the AEYE-DS device was also assessed in a human factors validation study with the Optomed Aurora handheld camera, including User Manual comprehension and usability of the device in the hands of potential users. Once the users underwent initial, one-time training and practice, all users stated that the device was easy and straightforward and all were successful in submitting images for diagnosis and obtaining a diagnosis output result and PDF report. All users stated that the user manual was clear and easy to use.

In summary, the AEYE-DS device using images acquired from the Optomed Aurora fundoscopy device demonstrates successful performance, in terms of sensitivity, specificity, PPV and NPV, as well as imageability, usability, and precision.

Substantial Equivalence:

The subject AEYE-DS device, manufactured by AEYE Health Inc., is substantially equivalent to the cleared AEYE-DS device (also manufactured by AEYE Health Inc. and the subject of 510(k) K221183).

Table 1: Comparison of the AEYE-DS Device to the predicate AEYE-DS Device (K221183)

Technological Characteristic	AEYE-DS Device (K221183)	AEYE-DS Device (K240058)
Product Code, Class	PIB Class II	Same
Indications for Use	The AEYE-DS is indicated for use by health care providers to automatically detect more than mild diabetic retinopathy (mtmDR) in adults diagnosed with diabetes who have not been previously diagnosed with diabetic retinopathy. The AEYE-DS is indicated for use with the Topcon NW400.	AEYE-DS is indicated for use by health care providers to automatically detect more than mild diabetic retinopathy (mtmDR) in adults diagnosed with diabetes who have not been previously diagnosed with diabetic retinopathy. AEYE-DS is indicated for use with the Topcon NW400 camera and Optomed Aurora camera.
Target Population	Adult subjects diagnosed with Diabetes	Adult subjects diagnosed with Diabetes
Anatomical Sites	Eye examination	Same
Environment Used	Hospitals, Clinics	Same
Energy Used / Delivered	Not Applicable	Same
Design:	A fundus camera is attached to a computer, where the AEYE-DS Client module is installed. The Client module allows the user to interact with the server-based analysis software over a secure internet connection. Using the Client module, users identify one (macular) or two (macular and disc) fundus images per eye to be dispatched to the Service module. The Service is installed on a server hosted at a secure datacenter. The Analytics module, which runs alongside the Service module, processes the fundus images and returns information on the image quality and the presence or absence of mtmDR to the Service module. The Service then returns the results to the Client module.	A fundus camera is attached to a computer, where the AEYE-DS Client module is installed. The Client module allows the user to interact with the server-based analysis software over a secure internet connection. Using the Client module, users identify one (macular) or two (macular and disc) fundus images per eye to be dispatched to the Service module. One macular image per eye is required for the Topcon NW400 camera or the Optomed Aurora camera. Two (macular and disc) images per eye are optionally used only for the Topcon NW400 camera. The Service is installed on a server hosted at a secure datacenter. The Analytics module, which runs alongside the Service module, processes the fundus images and returns information on the image quality and the presence or absence of mtmDR to the Service module. The Service then returns the results to the Client module.

Technological Characteristic	AEYE-DS Device (K221183)	AEYE-DS Device (K240058)	
-Mechanism of Action	Artificial Intelligence software as a medical device	Same	
- Components	The AEYE-DS device consists of the following components: - Client software on computer connected to fundoscopy camera - Server including Service software and Analytics software	Same	
- Inputs	Macula and disc centered color fundus images with at least 45º field of view, 2 images per eye; Or Macula centered color fundus images with at least 45º field of view, 1 image per eye.	Macula and disc centered color fundus images (2 images per eye) with at least 45º field of view (for the Topcon NW400); Or Macula centered color fundus images (1 image per eye) with at least 45º field of view (for the Topcon NW400 camera) or with at least 50 by 40º field of view (for the Optomed Aurora camera).	
- Outputs	More than mild diabetic retinopathy (mtmDR) detected, not detected or insufficient quality	Same	
- Indicated Cameras	Topcon NW400 camera	Topcon NW400 camera or Optomed Aurora camera	
Performance	Topcon NW400: Sensitivity: 93% Specificity: 91% Imageability: 99% PPV: 60% NPV: 99%	Optomed Aurora Study 1: Sensitivity: 92% Specificity: 94% Imageability: 99% PPV: 68% NPV: 99%	Optomed Aurora Study 2: Sensitivity: 93% Specificity: 89% Imageability: 99% PPV: 53% NPV: 99%
Human Factors	The AEYE-DS device uses the Client module as the user interface. The safe and efficient use of the device was established in a Usability study with novice operators.	Same	
Standards Met	IEC 62304 and FDA Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices ISO 14971 FDA Guidance - Content of Premarket Submissions for Management of Cybersecurity in Medical Devices	Same	

Technological Characteristic	AEYE-DS Device (K221183)	AEYE-DS Device (K240058)
Materials	No patient contacting materials	Same
Biocompatibility	Not Applicable	Same
Compatibility With the Environment and Other Devices	The AEYE-DS device is compatible for use with the Topcon NW400 device. Compatibility with the environment is not applicable.	The AEYE-DS device is compatible for use with the Topcon NW400 or Optomed Aurora device. Compatibility with the environment is not applicable.
Sterility	Not Applicable	Same
Electrical Safety	Not Applicable	Same
Mechanical Safety	Not Applicable	Same
Chemical Safety	Not Applicable	Same
Thermal Safety	Not Applicable	Same
Radiation Safety	Not Applicable	Same

Conclusions:

The subject AEYE-DS device, manufactured by AEYE Health Inc., is substantially equivalent to the cleared AEYE-DS device (also manufactured by AEYE Health Inc. and the subject of 510(k) K221183).

The subject AEYE-DS device has the same intended use and indications for use as the cleared AEYE-DS device. The subject device and the cleared AEYE-DS device are similar in terms of their intended prescription use only, suitable for the adult population diagnosed with diabetes, indicated for use in the same anatomical site (i.e., for eye examinations) and to be used in hospital or clinic settings.

The predicate AEYE- DS device is compatible for use with the Topcon NW400 device, whereas the subject AEYE-DS device is compatible for use with the Topcon NW400, as well as the Optomed Aurora camera.

The subject AEYE-DS and cleared AEYE-DS devices are composed of the same components, including a Client module, and a Server including the Service and Analytics modules. The subject AEYE-DS device has the same mechanism of operation and uses the same underlying technology as the predicate AEYE-DS device. That is, a user interface Client module communicates with the Server, where the fundus images (one macular centered image per eye for the Topcon NW400 camera and the Optomed Aurora camera; or one macular centered and one disc centered image per eye for the Topcon NW400 only) are received and analyzed in the Analytics module to provide information regarding the presence or absence of mtmDR, which

is returned to the Client module. Both the AEYE-DS devices are based on Artificial Intelligence (AI) software as a medical device and use the identical software algorithm for detecting the presence or absence of more than mild Diabetic Retinopathy in diabetic patients.

The performance characteristics, including the sensitivity, specificity, imageability, PPV and NPV of the subject AEYE-DS device using the Optomed Aurora camera are substantially equivalent to the cleared AEYE-DS device using the Topcon NW400 camera, as demonstrated in the clinical studies performed with the AEYE-DS device. The human factors incorporated into the subject AEYE-DS device and the cleared AEYE-DS device are the same. Both devices use the Client module as the user interface and the safe and efficient use of the device was established in a Usability study with novice operators for both devices.

The subject device, as the cleared device, complies with same relevant consensus standards and FDA guidance document requirements, including the special controls, software validation, cybersecurity and risk analysis.

In summary, the subject AEYE-DS device intended use, technological characteristics and clinical performance are substantially equivalent to the predicate AEYE-DS device. Consequently, it can be concluded that the subject AEYE-DS device is substantially equivalent to the predicate AEYE-DS device, cleared in 510(k) K221183 and therefore, the subject AEYE-DS device may be legally marketed in the USA.