December 9, 2024

Verily Life Sciences, LLC
℅ Prithul Bom
Most Responsible Person
Regulatory Technology Services, LLC
1000 Westgate Drive,
Suite 510k
Saint Paul, Minnesota 55114

Re: K242508
Trade/Device Name: Verily Numetric Retinal Camera
Regulation Number: 21 CFR 886.1120
Regulation Name: Ophthalmic Camera
Regulatory Class: Class II
Product Code: HKI
Dated: November 13, 2024
Received: November 13, 2024

Dear Prithul Bom:

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.

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,

Elvin Y. Ng -S 2024.12.09 17:29:55 -05'00'

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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K242508

Device Name

Verily Numetric Retinal Camera

Indications for Use *(Describe)*

Verily Numetric Retinal Camera is a non-contact, high resolution digital imaging device which is suitable for photographing, displaying and storing images of the retina segment of the eye to be evaluated under non-mydriatic conditions.

Verily Numetric Retinal Camera is indicated for in-vivo viewing of the posterior segment of the eye. The images are intended for use as an aid to clinicians in the evaluation, diagnosis, and documentation of ocular health.

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
K242508

This summary of Traditional 510(k) safety and effectiveness information is submitted in accordance with the requirements of SMDA 1990 and 21 CPR 807.92.

Date Prepared	December 9, 2024
Submitter	Verily Life Sciences, LLC
Official Contact	Pooja Shah, Regulatory Affairs Specialist 269 E Grand Avenue, South San Francisco, California, 94080 Email: shahpoo@verily.com
Proprietary Name	Verily Numetric Retinal Camera
Common Name	Ophthalmic Camera
Classification	Class II Medical Device Regulation Number: 21 CPR 886.1120 Product Code: HKI
Predicate Device	K182199, NFC-700 Non-Mydriatic Auto Fundus Camera Regulation Number: 21 CPR 886.1120

Indications for Use

Verily Numetric Retinal Camera is a non-contact, high resolution digital imaging device which is suitable for photographing, displaying and storing images of the retina segment of the eye to be evaluated under non-mydriatic conditions.

Verily Numetric Retinal Camera is indicated for in-vivo viewing of the posterior segment of the eye. The images are intended for use as an aid to clinicians in the evaluation, diagnosis, and documentation of ocular health.

Device Description

The Verily Numetric Retinal Camera (VNRC), the subject device, is a tabletop fundus camera that provides non-mydriatic, color, posterior segment images of the eye as an aid to clinicians in the evaluation and diagnosis of eye disease. It is a non-contact, high-resolution digital imaging device that is suitable for photographing, displaying, and storing images of the retina to be evaluated under non-mydriatic conditions.

The Verily Numetric Retinal Camera takes images of the fundus in the following manner:

Focusing: The patient interactively focuses an image shown on a microdisplay to the best qualitative focus by turning a knob on an external peripheral device which modulates the camera optics.

Alignment: The patient is shown a fixation target on the microdisplay and through an interactive session with position feedback, the patient aligns their pupil to the camera. The pupil location is determined using eye-tracking.

Image Capture: White light from LEDs illuminates the fundus. The light reflection from the fundus is captured by a color CMOS sensor.

Safety

All safety-related parameters of Verily Numetric Retinal Camera, such as light hazard protection, material biocompatibility, and IEC-60601 compliance, have been tested and conform to industry standards. The Verily Numetric Retinal Camera has the same analysis features as the predicate device; and all related test reports of safety show the Verily Numetric Retinal Camera is compliant with the same safety standards declared by the predicate device, NFC-700.

Biocompatibility Testing

The biocompatibility evaluation for Verily Numetric Retinal Camera has been conducted in accordance with ISO 10993-1.

Effectiveness

The validation of effectiveness for the Verily Numetric Retinal Camera has been analyzed in detail and the image quality is similar to the predicate device. The results demonstrate that the Verily Numetric Retinal Camera is as effective as the predicate device, NFC-700.

Substantial Equivalence Discussion

Verily Numetric Retinal Camera is substantially equivalent to the predicate device, Crystalvue's NFC-700 Non-Mydriatic Auto Fundus Camera (a.k.a NFC-700) (Kl82199), as both the subject and predicate devices are intended as an aid to clinicians in the evaluation and diagnosis of eye disease. Both devices are indicated for photographing, displaying and storing images of the retina to be evaluated under non-mydriatic conditions. Similar to the predicate device, the subject device is classified as "Ophthalmic Camera" in accordance with 21 CPR 886.1120, Product Code HKI.

It is important to note that the method of alignment of the predicate device, NFC-700 camera is automatic, and that of the Verily Numetric Retinal Camera is interactive. The focusing on the Verily Numetric Retinal Camera is performed by the patient viewing a screen which is collocated in the same plane as the image sensor. It ensures that the fundus image is in sharp focus on the image sensor. These differences do not limit the camera's ability to be safe and effective.

The table below is a comparative summary of the similarities and differences between the Verily Numetric Retinal Camera (subject device) and the NFC-700 camera (predicate device) (Kl82199).

Product Item	Verily Numetric Retinal Camera	Crystalvue, NFC-700 Non- Mydriatic Auto Fundus Camera	Comparison Comments
510(k) number	K242508	K182199	
Intended Use	Verily Numetric Retinal Camera provides non-mydriatic, color posterior segment images of the eye as an aid to clinicians in the evaluation and diagnosis of eye disease.	NFC-700 provides non-mydriatic, color posterior chamber and external images of the eye as an aid to clinicians in the evaluation and diagnosis of eye disease.	Verily Numetric Retinal Camera does not acquire external images of the eye for sharing with the end users. The camera acquires and shares retinal images only. All else is identical.
Indication for Use	Verily Numetric Retinal Camera is a non-contact, high resolution digital imaging device which is suitable for photographing, displaying and storing images of the retina segment of the eye to be evaluated under non-mydriatic conditions. Verily Numetric Retinal Camera is indicated for in-vivo viewing of the posterior segment of the eye. The images are intended for use as an aid to clinicians in the evaluation, diagnosis, and documentation of ocular health.	NFC-700 is a non-contact, high resolution digital imaging device which is suitable for photographing, displaying and storing images of the retina and external areas of the eye to be evaluated under non-mydriatic conditions. NFC-700 is indicated for in-vivo viewing of the posterior and external area of the eye and the images are intended for use as an aid to clinicians in the evaluation, diagnosis and documentation of ocular health.	Verily Numetric Retinal Camera does not acquire external images of the eye. All else is identical.

Where Used	Professional healthcare environment	Hospital	The camera has been demonstrated to be safe and effective in healthcare environments.
Design			
Shape	Verily Numetric Retinal Camera and Chromebook	All in one	No significant differences. Minor hardware differences of the operator display do not raise different questions of safety and effectiveness.
Dimensions (WxDxH)	257 x 420 x 360 (mm)	282 x 485 x 492 (mm)	No significant differences. Minor hardware differences do not raise different questions of safety and effectiveness
Weight	6 kg	17 kg	Physical weight of the device do not raise different questions of safety and effectiveness.
Eye Fixation	One (1) fixation point	10 fixation points	Verily Numetric Retinal Camera is designed to be used with a single automated visual fixation point. Both VNRC and predicate are able to provide gradable images to aid clinicians in the evaluation and diagnosis of eye disease. The difference in number of automated fixation points does not limit the safety and effectiveness of the device.
Power Supply	AC 100V to 240V, 50/60Hz (Auto selected)	AC 100V to 240V, 50/60Hz (Auto selected)	Same
Environment	Temp.: 15-30 °C / Humidity: 20-75%RH	Temp.: 10-35 °C / Humidity: 30-90%RH	No significant difference. Professional healthcare environments are within the environmental ranges of both cameras.

Light source I.Observation: 2. Flash:	1. Infrared LED 2. White LED	1. Infrared LED 2. White LED	Same
Type of Photography	Color posterior eye image	Color / Digital red-free / Anterior eye image	The Verily Numetric Retinal Camera only acquires color images of the posterior segment.
Operation Principle	The Verily Numetric Retinal Camera takes images of the fundus in the following manner: **I.Focusing:** The patient interactively focuses an image shown on a microdisplay (located at the same optical plane as the image sensor) into best qualitative focus by turning a knob on an external peripheral device which modulates the camera optics. **2. Image Capture:** The patient is shown a fixation target and through an interactive session with position feedback, the patient aligns their pupil to the camera. The pupil location is determined using eye-tracking. White light from LEDs illuminate the fundus. The light reflection from the fundus is captured by a color CMOS sensor.	The optical design of fundus camera is based on the principle of monocular indirect ophthalmoscopy. **1. Fundus observation:** A built in light ray from the infrared light LED source to illuminate the fundus. Alignment of the device is performed by a built- in eye tracking indicator and working distance indicator to adjust the system to the best XYZ position automatically. **2. Image capture:** System uses split-image technique to do image focus adjustment automatically to capture the best quality of image. White light from LEDs Flash module irradiates the fundus. The light reflected from eye portions forms an image, and	The method of alignment of the NFC-700 is automatic, and that of the Verily Numetric Retinal Camera is interactive. The focusing is performed by the user viewing a screen which is collocated in the same plane as the image sensor, it ensures that the fundus image is in focus on the image sensor. These differences do not limit the camera's ability to be safe and effective.

		the image is captured by built-in color CMOS camera module for fundus image capture.	
Material of Chinrest	No Chinrest	ABS	There is no chin rest for the Verily Numetric Retinal Camera device.
Material of Forehead Rest	Silicone	TPE	The Verily Numetric Retinal Camera device contains a facerest that contacts the forehead and cheek area. The biocompatibility has been tested by a recognized lab, thus there is no impact to safety.
Safety	Compliance with • IEC 60601-1	Compliance with • IEC 60601-1	Same
EMC	Compliance with IEC 60601-1-2	Compliance with • IEC 60601-1-2	Same
Performance			
Image (resolution)	2.1 MP	12MP	The difference in image resolution does not affect the safety and effectiveness of the device. The VNRC camera meets all optical performance specifications recommended by ISO 10940 standard.
Alignment	Interactive Guided Alignment	Fully automatic 3D tracking	The captured image is brought into focus and alignment interactively by the patient for the Verily Numetric Retinal Camera instead of automatically by the instrument for the NFC-700. The differences in the method of

			alignment does not affect the safety and effectiveness of the device.
Field-of-View	45°	45°	Same
Minimum Pupil Size	3.0 mm	4.0 mm	The Verily Numetric Retinal Camera is able to image patients with smaller pupils than the predicate. This difference does not limit the camera's ability to be safe and effective.
Operation Range (Focus Adjustment Range): 1. Without compensation lens: 2. With compensation lens:	-20 to +20D (no compensation lens)	-15 to +10D -30D to -10D or +5D to +30D	Verily Numetric Retinal Camera passes the ISO 10940 specification of+/- 15D without the need of a compensation lens. The difference does not affect safety and effectiveness.
Interface	USB2.0 / Wi-Fi	USB2.0 /Ethernet/ HDMI	Differences in data modality transfer do not impact the safety and effectiveness of the device.

The differences in technological characteristics associated with the subject device and the predicate device, NFC-700 (K182199) have been evaluated through performance testing for the target population and there are no new questions of safety and effectiveness. Therefore, the subject device is substantially equivalent to the predicate device.

Non-Clinical Performance Data

Non-clinical performance testing for the Verily Numetric Retinal Camera includes analysis using raw data collected via a retrospective clinical study. Bench testing includes verification and validation of specifications. All tests confirmed that the subject device met the predetermined acceptance criteria and that the features driving performance are substantially equivalent to those present in the specified predicate device.

The Verily Numetric Retinal Camera has been tested and found to be in full compliance with the following FDA-recognized consensus standards:

- ANSI Z80.36-2021 (Group 1 Instrument)
- ISO 10940 Second edition 2009
- IEEE ANSI C63.27-2017
- AAMI TIR69:2017/(R2020)

Software Validation

The software verification and validation testing were conducted and documentation was provided as recommended by IEC-62304:2015, "Medical Device Software- Software Life Cycle Processes." The software for Verily Numetric Retinal Camera is classified as Class A according to the classification criterion of IEC 62340:2015, and has been evaluated to be Basic Documentation Level as per FDA Guidance document - "Content of Premarket Submissions for Device Software Functions (June 2023)." Software used in the Verily Numetric Retinal Camera conforms to the safety principles and is demonstrated through the risk management process for medical devices.

Bench Testing Summary:

The VNRC has undergone performance testing before release to ensure that the device hardware and its software meet the functional requirements and to demonstrate equivalence to the predicate device.

A summary of the results of performance testing and the device requirements follows:

Performance Item	Verily Numetric Retinal Camera Acceptance Criteria	Test Result
Resolving power	≥ 60 line pairs/mm at the center of the field ≥ 40 line pairs/mm at the mid field (r/2) ≥25 line pairs/mm at the periphery of the field (r)	Pass

Field of view	45 degrees	Pass
Pixel pitch tolerance	<7%	Pass
Alignment illumination	The alignment illumination is done via Near	Pass

	Infrared (NIR) LEDs during eye tracking. The intensity of the NIR LEDs is controlled by SW.	
Flash illumination	The flash illumination is done via white LEDs during the image capture. The intensities and durations of the white LEDs are controlled by SW.	Pass
Range of focus	-20D to +20D (no compensating lens)	Pass
Minimum pupil size	3.0mm	Pass
Alignment	Interactive alignment using 3D tracking.	Pass
Image quality	The gradability of images captured by VNRC is comparable to the predicated device on the same population.	Pass

Conclusion

In summary, the comprehensive testing and analysis demonstrates that the Verily Numetric Retinal Camera is safe and effective for the specified intended use. This testing, in addition to the comprehensive comparison to the predicate device, NFC-700 (K182199), demonstrates the Verily Numetric Retinal Camera is substantially equivalent to the predicate device.