August 14, 2025

Forus Health Pvt.ltd.,
Rj Venkataramanan
Cmo & Ro
No. 8, 27th Cross Rd, Banashankari Stage II, Banashankari
Bengaluru, Bengaluru 560070
India

Re: K243600
Trade/Device Name: 3nethra neo HD FA; 3nethra neo HD
Regulation Number: 21 CFR 886.1120
Regulation Name: Ophthalmic Camera
Regulatory Class: Class II
Product Code: HKI
Dated: November 21, 2024
Received: November 21, 2024

Dear Rj Venkataramanan:

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

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)*

K243600

Device Name

3nethra neo HD FA;
3nethra neo HD

Indications for Use *(Describe)*

3nethra neo HD FA:

3nethra neo HD FA is used as a wide-field retinal imaging digital camera for photo documentation of ocular diseases that manifest in infants. The device acquires only images and does not provide any pathological analysis or diagnosis for treatment.

3nethra neo HD:

3nethra neo HD is used as a wide-field retinal imaging digital camera for photo documentation of ocular diseases that manifest in infants. The device acquires only images and does not provide any pathological analysis or diagnosis for treatment.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) SUMMARY

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR 807.92

1. General Information

Applicant	Forus Health Pvt. Ltd
Applicant's Address	No.8, 27th Cross Rd, Banashankari Stage II, Banashankari, Bengaluru, Karnataka, INDIA 560070
Phone Contact	+91 80 69439999
FAX	+91 80 6943 9943
Contact Person & Email	RJ Venkataramanan quality@forushealth.com
Date Prepared	14-08-2025
Common Name	Ophthalmic Camera
Trade Name and Model	3nethra neo HD FA 3nethra neo HD
Device Classification	2
Product Code	HKI
Classification Name	Camera, Ophthalmic, Ac-powered
Regulation Number	886.1120
Classification Panel	Ophthalmic
Predicate Device	3nethra neo (K183059)

2. Device Description

3nethra neo HD FA:

The 3nethra neo-HD FA is a handheld wide-angle fundus imaging system for neonatal screening. It is designed to acquire, display, store and transmit images of the posterior and anterior surfaces of human eye. The images assist clinicians in the evaluation and documentation of visual health in retinopathy of prematurity (ROP) and other problems. It operates in contact with the cornea of the eye under test. 3nethra neo HD FA uses continuous white light for operation and hence need pupil dilation. It also equipped with blue light source and green filters for fundus fluorescein angiography (FFA).

3nethra neo HD:

The 3nethra neo-HD is a handheld wide-angle fundus imaging system for neonatal screening. It is designed to acquire, display, store and transmit images of the posterior and anterior surfaces of human eye. The images assist clinicians in the evaluation and documentation of visual health in retinopathy of prematurity (ROP) and other problems. It operates in contact with the cornea of the eye under test. 3nethra neo HD uses continuous white light for operation and hence need pupil dilation. The 3nethra neo HD is a lower end variant of the 3nethra neo HD FA without the Fluorescein Angiography feature.

3. Indication for Use

3nethra neo HD FA:

3nethra neo HD FA is used as a wide-field retinal imaging digital camera for photo documentation of ocular diseases that manifest in infants. The device acquires only images and does not provide any pathological analysis or diagnosis for treatment.

3nethra neo HD:

3nethra neo HD is used as a wide-field retinal imaging digital camera for photo documentation of ocular diseases that manifest in infants. The device acquires only images and does not provide any pathological analysis or diagnosis for treatment.

4. Substantial Equivalence Summary and Predicate Device

Based on our evaluation of substantial equivalence, The design of 3nethra neo HD FA/ 3nethra neo HD is substantially equivalent to the design of the predicate device. The methods of operation is based on well-established methods of use currently available in the market.

- **Primary Predicate**

  Device Name: 3nethra neo (K183059)
  Device Class: Class II
  Product Code: HKI
  Applicant: Forus Health Pvt.Ltd.

- **Reference Device**

  Device Name: RetCam 3 Ophthalmic Imaging System (K102859)
  Device Class: Class II
  Product Code: HKI
  Applicant: Clarity Medical Systems

➢ Technological Similarities

Technological Characteristics	**Subject Device**		**Primary Predicate**	**ReferenceDevice**	**Equivalence**
Device Name	3nethra neo HD FA	3nethra neo HD	3nethra neo (K183059)	Retcam 3 Ophthalmic Imaging System (K102859)	N/A
	Design				
Feature	White andblue	White and blue	White light module	White light module	Equivalent to the Primary Predicate.
	Camera				
Field of view	150 degrees	150 degrees	120 degrees	30 to 130 degrees	Different, but does not add any new concerns regarding the

					safety and efficacy of the device
	Light Source				
Light source type	White and blue LED	White and blue LED	White light LED	White light LED	Equivalent to the Primary Predicate.
Light intensity control	Zero to maximum	Zero to maximum	Zero to maximum	Zero to maximum	Equivalent to the Primary Predicate.
External fixation light (if any)	None	None	None	None	N/A
	Electrical				
Power Supply	AC 100-240 V, 50/60 Hz	AC 100-240 V, 50/60 Hz	AC 100-240 V, 50/60 Hz	AC 100-240 V, 50/60 Hz	Equivalent to the Primary Predicate.
	Operating Conditions				
Insert filter	Software controlled Motorized blue filter	Software controlled Motorized blue filter	No insert filter needed	Insert filter needed for FA mode	Equivalent to the Reference Device
Imaging Format	PNG/.jpeg (after export)/.DCM(after export)	PNG/.jpeg (after export)/.DCM(after export)	PNG/.jpeg (after export)/.DCM(a fter export)	TIF/.JPEG/.AVI/.BMP	Equivalent to the Primary Predicate.
	Safety				
Safety Compliance	IEC 60601-1 IEC 60601-1-2	IEC 60601-1 IEC 60601-1-2	IEC 60601-1 IEC 60601-1-2	IEC 60601-1 IEC 60601-1-2	Equivalent to the Primary Predicate.

Technological Difference

Technological Characteristics	**Subject Device**		**Primary Predicate**	**Reference Device**	**Equivalence**
Device Name	3nethra neo HD FA	3nethra neo HD	3nethra neo (K183059)	Retcam 3 Ophthalmic Imaging System (K102859	N/A
	Design				
Feature	Fluorescence Angiography module	No Fluorescence Angiography module	No Fluorescence Angiography module	Fluorescence Angiography module	Equivalent to the Reference device

These technological differences do not alter the intended use of the device, nor do they affect the safety and effectiveness of the device relative to the primary predicate device.

5. Bench Test Summary

- **Electrical safety and electromagnetic compatibility**- Electrical safety and EMC testing were conducted on the 3nethra neo HD FA /3nethra neo HD in accordance with established protocols. The device complies with IEC 60601-1 for electrical safety and IEC 60601 standard for EMC.

- **Light safety testing-** The 3nethra neo HD FA /3nethra neo HD evaluated for compliance to standard ISO 15004-2- Ophthalmic Instruments - Fundamental requirements and test methods and ANSI Z80.36. The evaluation demonstrates compliance with Group 1 instrument requirements provided by the standards.

- **Animal Testing:**

  Biocompatibility testing- The biocompatibility evaluation for the 3nethra neo HD FA /3nethra neo HD is not required as the part that comes in contact with the patient is identical to the Primary Predicate device. There is no difference in any characteristics of the part and is completely identical with the Primary Predicate. The primary predicate is our own device hence the biocompatibility assessment done during the Primary predicate holds good for the Subject Device.

6. Clinical Performance Data

- **Image Quality:**

  A clinical observational study was performed to compare the quality of fluorescein angiography (FA) images produced by the 3nethra neo HD FA subject device and the RetCam 3 reference device (cleared under K182263). The primary objective of the study was to demonstrate that FA images produced by the 3nethra neo HD FA are substantially equivalent in safety and effectiveness to those produced by a cleared neonatal fundus camera reference device. The results of the image quality comparison study demonstrated that of all study images were found to be of comparable quality to those produced by the reference device supporting substantial equivalence of the subject device as safe and effective for its intended use.

7. Conclusion on Bench tests and Clinical Performance Data

The bench tests and clinical performance data supports our conclusion of substantial equivalence of 3nethra neo HD FA /3nethra neo HD to the mentioned predicate devices.