December 21, 2018

Forus Health Pvt. Ltd.
Shruti Kashinath
Lead, Quality and Regulatory
#86/2, Ground Floor, Dvg Smaraka Bhavana, Bull Temple Road
5th Main Nr Colony
Bengalura, 560019 In

Re: K183059
Trade/Device Name: 3nethra neo
Regulation Number: 21 CFR 886.1120
Regulation Name: Ophthalmic Camera
Regulatory Class: Class II
Product Code: HKI,
Dated: October 29, 2018
Received: November 2, 2018

Dear Shruti Kashinath:

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 (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 located 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.

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 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely yours,

Bradley S. Cunningham -S

for Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K183059

Device Name
3nethra neo

Indications for Use *(Describe)*
3nethra neo is used as a wide field retinal imaging digital camera for photo documentation of ocular diseases that manifest in infants.

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

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	#86/2, Ground Floor, Dvg Smaraka Bhavana, Bull Temple Road, 5th Main Nr Colony Bengaluru, Karnataka, INDIA 560019
Phone Contact	+91 80 4162 4041 | 4162 4042
FAX	+91 80 4206 5393
Contact Person & Email	Shruti Kashinath shruti@forushealth.com
Date Prepared	Oct-10-2018
Common Name	Ophthalmic Camera
Trade Name and Model	3nethra neo
Device Classification	2
Product Code	HKI
Classification Name	Camera, Ophthalmic, Ac-powered
Regulation Number	886.1120
Classification Panel	Ophthalmic
Predicate Devices	Retcam3 Ophthalmic Imaging System (K102859) Phoenix Clinical ICON (K170527)

2. 3nethra neo Device Description

The 3nethra neo is a compact, portable and easy to use, mydriatic, digital wide field imaging camera used for the photo documentation of ocular diseases that manifest in infant eyes. 3nethra neo needs to be connected to a computer for running the application software, to store, view, retrieve, and export the digital ophthalmic images. The 3nethra neo has a hand-held probe unit, a control box and a foot-pedal control unit. Warm white LED with intensity control via foot-pedal is used to provide illumination to the eye in order to capture images.

3. Indications for Use

3nethra neo is used as a wide field retinal imaging digital camera for photo documentation of ocular diseases that manifest in infants.

4. Substantial Equivalence Summary and Predicate Device

The design of 3nethra neo is substantially equivalent to the design of the predicate device. The methods of action and use are identical and the user functions are all identical in functionality between the 3nethra neo and the predicate.

- **Primary Predicate:**
  Device Name: RetCam 3 Ophthalmic Imaging System (K102859)
  Device Class: Class II
  Product Code: HKI
  Applicant: Clarity Medical Systems
- **Secondary Predicate:**
  Device Name: Phoenix Clinical Icon (K170527)
  Device Class: Class II
  Product Code: HKI
  Applicant: Phoenix Technology Group

- **Technological Similarities**

Technological Characteristics	**3nethra neo**	**Retcam 3 Ophthalmic Imaging System (K102859)**	**Phoenix Clinical ICON (K170527)**
Design			
Feature	White light module	White light module	White Light Module
Camera			
Field of view	120 degrees	30 to 130 degrees	100 degrees
Frame rate	>=20 fps	30 fps	30 fps
Light Source			
Light source type	White light LED	White light LED	White light LED
Light intensity control	Zero to maximum	Zero to maximum	Zero to maximum
Maximum light source output power	6.04mW/cm^2	21 mW/cm^2	6.1 mW/cm^2
External fixation light (if any)	None	None	None
Electrical			
Power Supply	AC 100-240 V, 50/60 Hz	AC 100-240 V, 50/60 Hz	AC 100-240 V, 50/60 Hz
Operating Conditions			
Insert filter	No insert filter needed	No insert filter needed	No insert filter needed
Imaging Format	.PNG/.jpeg (after export)/.DCM(after export)	.TIF/.JPEG/.AVI/.BMP	.TIF/.JPEG/.AVI
Safety			
Safety Compliance	IEC 60601-1, IEC 60601-1-2	IEC 60601-1, IEC 60601-1-2	IEC 60601-1 IEC 60601-1-2

- **Technological Differences**

Technological Characteristics	**3nethra neo**	**Retcam 3 Ophthalmic Imaging System (K102859)**	**Phoenix Clinical ICON (K170527)**
Design			
Feature	No Fluorescence Angiography module	Fluorescence Angiography module	Fluorescence Angiography module

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 predicate.

5. Bench Test Summary

- **Electrical safety and electromagnetic compatibility**:
  Electrical safety and EMC testing was conducted on the 3nethra neo in accordance with established protocols. The device complies with IEC 60601-1 for electrical safety and IEC 60601-1-2 standard for EMI/EMC.

- **Light safety testing:**
  The 3nethra neo was evaluated for compliance to:
  - ISO 15004-2- Ophthalmic Instruments - Fundamental requirements and test methods, and
  - ANSI Z80.36-American National Standard for Ophthalmics - Light Hazard Protection for Ophthalmic Instruments.

  The evaluation demonstrates compliance with Group 1 instrument requirements provided by the standards.

- **Performance Testing:**
  - The methodologies prescribed by ISO 10940 were used to evaluate the fundus imaging performance of our device.
  - The central resolving power of 3nethra neo was verified and found to be greater than 60 lp/mm. Also, resolving power requirements for the full FOV region were verified using an artificial eye and clinical setups.

  The measured results are supportive of substantial equivalence to the predicate devices.

- **Animal Testing:**

  Biocompatibility testing:

  The biocompatibility evaluation for the 3nethra neo was done through animal studies. The studies demonstrated compliance with the following standards:

  - ISO 10993-10:2010 – Skin Sensitization
  - ISO 10993-10:2010 - Intracutaneous Reactivity
  - ISO 10993-5:2009 - Cytotoxicity

6. Clinical Performance Data

- **Method:** 128 premature Asian Indian Infants from 35 neonatal centers were screened using the RetCam and the "3nethra neo" alternately with either device first. A minimum of seven images from each eye including the dilated anterior segment was obtained from each device. Images from the "3nethra neo" were cropped to resemble those of the RetCam. Two RO specialists masked to the origin of the randomly presented images were provided with birth weights (BW), gestational age (GA) and post menstrual ages (PMA) at imaging. They reported the presence of retinal immaturity, maturity or on the stage of Retinopathy of Prematurity (ROP) and zone of involvement, for each eye, in each session and reached a 'decision' on whether to treat, follow-up or discharge the baby based on the findings in both eyes.

- **Result:** 144 sessions of 128 infants (73 male: 55 female) were analyzed. The mean for BW was 1485 grams, GA was 31.1 and PMA was 40.2 weeks respectively. The '3nethra neo' had a sensitivity of 97.4 and 99.3 and a specificity of 81.1 and 75.6 for detecting any stage ROP for the two observers respectively. The kappa for clinical decision and agreement were 0.60 and 79% and 0.90 and 95% for the two observers respectively. Inter rater agreeability for staging was 0.8 and 73.4% agreement. Both observers correctly identified all (n=27) zone 3 diseases on the '3nethra neo' images.

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 to the mentioned predicate devices.