April 13, 2021

Natus Medical Incorporated DBA Excel-Tech Ltd. (Xltek)
Sanjay Mehta
Director of Global Regulatory Affairs, QARA
2568 Bristol Circle
Oakville, Ontario L6H 5S1
Canada

Re: K203500
Trade/Device Name: RetCam Envision
Regulation Number: 21 CFR 886.1120
Regulation Name: Ophthalmic Camera
Regulatory Class: Class II
Product Code: HKI
Dated: March 9, 2021
Received: March 10, 2021

Dear Mr. Mehta:

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/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 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 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)*
K203500

Device Name
RetCam Envision

Indications for Use *(Describe)*
General ophthalmic imaging including retinal, corneal, and external imaging.
• Photodocumentation of pediatric ocular diseases, including retinopathy of prematurity (ROP).
• Screening for Type 2 pre-threshold retinopathy of prematurity (ROP) (zone 1, stage 1 or 2, without plus disease, or zone 2, stage 3, without plus disease), or treatment-requiring ROP, defined as Type 1 ROP (zone 1, any stage, with plus disease; zone 1, stage 3 without plus disease; or zone 2, stage 2 or 3, with plus disease), or threshold ROP (at least 5 contiguous or 8 non-contiguous clock hours of stage 3 in zone 1 or 2, with plus disease) * in 35-37 week postmenstrual infants.

* References:
1. Cryotherapy for Retinopathy of Prematurity Cooperative Group. Multicenter trial of cryotherapy for retinopathy of prematurity: preliminary results. Archives of Ophthalmology 1988; 106(4): 471-479.
2. Early Treatment for Retinopathy of Prematurity Cooperative Group. Revised indications for the treatment of retinopathy of prematurity: results of the Early Treatment for Retinopathy of Prematurity Randomized Trial. Archives of Ophthalmology 2003; 121(12):1684-1694.

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.

510K Summary

Date: April 11, 2021

Submitted by: Natus Medical Incorporated
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Proprietary Name: RetCam Envision™

Common Name: Camera, Ophthalmic, Ac-Powered

Regulation Number : 21CFR 886.1120

Classification Name: Ophthalmic camera.

Product code: HKI

Device Class: II

Predicate Device: RetCam 3 ; RetCam Shuttle ; RetCam Portable (K182263)

Description:

Overview: RetCam Envision

The RetCam Envision system is a contact type wide-field fundus ophthalmic imaging system used for general ophthalmic imaging including retinal, corneal, and external imaging. Photodocumentation of pediatric ocular diseases, including retinopathy of prematurity (ROP).

Screening for Type 2 pre-threshold retinopathy of prematurity (ROP) (zone 1, stage 1 or 2, without plus disease, or zone 2, stage 3, without plus disease), or treatment-requiring ROP, defined as Type 1 ROP (zone 1, any stage, with plus disease; zone 1, stage 3 without plus disease; or zone 2, stage 2 or 3, with plus disease), or threshold ROP (at least 5 contiguous or 8 non-contiguous clock hours of stage 3 in zone 1 or 2, with plus disease) * in 35-37 week postmenstrual infants.

Operating Principle of the RetCam Envision

A fundus camera comprised of handpiece, detachable lens piece, LED light sources, control panel, footswitch and application software running on a PC are used to acquire still images and video of the eye. The LED light is used to illuminate the retina uniformly and the image is transferred from the handpiece to the PC for display storage, review & transfer. The camera focus and image light intensity as well as the image capture is controlled by the user via a button panel on the cart or a footswitch. Controls are also available via the keyboard mouse and touchscreen.

RetCam Envision features includes:

- Integrated Wide Field Digital Imaging System
- Light weight Handpiece with interchangeable lenses featuring RetCam light shaping technology
- 130 Degree Field Of View (FOV)
- Brilliant Color, Red Free, and Fluorescein Angiography (FA) imaging capabilities
- High Resolution Still Image and Video Capture via console, footswitch or touchscreen
- Height adjustable system cart with touchscreen display and battery operation
- Integrated, searchable patient database
- Bidirectional DICOM interface

System Setup Overview

The RetCam Envision Cart, Light Sources, Camera Handpiece, Lenses, Control panel, and Footswitch operate in conjunction with the RetCam 7 Software running on an onboard PC to enable the capture, review, annotation, storage, and transfer of images and video of the eye and it'

The LED light source provides illumination of the eye via the camera (handpiece and lenspiece). Still and video images are transmitted from the handpiece to the onboard PC for display on the monitor and storage on the PC. Image focus, illumination intensity and image/video capture are controlled by the user using either the buttons on the cart top control panel or via the footswitch. The user selects the white LED light source for color imaging and the blue LED light source for imaging during Fluorescein Angiography.

The user interacts with the RetCam software to enter or select patient demographics, start exams, capture images and video, review and select images for storage, exporting and transfer via bidirectional DICOM communication. The RetCam Envision display monitor is a touchscreen.

Device-patient interaction Accessories List:

The RetCam Envision is a contact type wide field fundus ophthalmic imaging system.

The lens piece concave tip is held over the eye which is covered in a transparent coupling gel. The lens tip is held in the gel so that there is no air gap between the lens tip and the eye to ensure no distortion of light or image capture. The RetCam Envision User Manual provides detailed instructions on the thorough cleaning and high level disinfection of the detachable lenses.

The Lenspiece is the only part of the device that may come in contact with the patient.

Indications for Use

General ophthalmic imaging including retinal, corneal, and external imaging.

- Photodocumentation of pediatric ocular diseases, including retinopathy of prematurity (ROP).
- Screening for Type 2 pre-threshold retinopathy of prematurity (ROP) (zone 1, stage 1 or 2, without plus disease, or zone 2, stage 3, without plus disease), or treatment-requiring ROP, defined as Type 1 ROP (zone 1, any stage, with plus disease; zone 1, stage 3 without plus disease; or zone 2, stage 2 or 3, with plus disease), or threshold ROP (at least 5 contiguous or 8 non-contiguous clock hours of stage 3 in zone 1 or 2, with plus disease) * in 35-37 week postmenstrual infants.

*References:

1. Cryotherapy for Retinopathy of Prematurity Cooperative Group. Multicenter trial of cryotherapy for retinopathy of prematurity: preliminary results. Archives of Ophthalmology 1988; 106(4):471-479.

2. Early Treatment for Retinopathy of Prematurity Cooperative Group. Revised indications for the treatment of retinopathy of prematurity: results of the Early Treatment for Retinopathy of Prematurity Randomized Trial. Archives of Ophthalmology 2003; 121(12):1684-1694.

Comparison to Predicate Device

Feature	Subject Device RetCam Envision	PREDICATE DEVICE RetCam Ophthalmic Imaging Systems (K182263)	Similarities or Differences
Indications for Use	General ophthalmic imaging including retinal, corneal, and external imaging. Photodocumentation of pediatric ocular diseases including retinopathy of prematurity (ROP) Screening for Type 2 pre-threshold retinopathy of Prematurity (ROP) (zone1, stage 1 or 2, without plus disease, or zone 2 stage 3 without plus disease) or treatmentrequiring ROP, defined as Type 1 ROP (zone 1, any stage, with plus disease; zone 1, stage 3 without plus disease; or zone 2, stage 2 or 3, with plus disease) or threshold ROP (at least 5 contiguous or 8 non-contiguous clock hours of stage 3 in zone 1 or 2, with plus disease)* in 35-37 week postmenstrual infants.	General ophthalmic imaging including retinal, corneal, and external imaging. Photodocumentation of pediatric ocular diseases including retinopathy of prematurity (ROP) Screening for Type 2 pre-threshold retinopathy of Prematurity (ROP) (zone1, stage 1 or 2, without plus disease, or zone 2 stage 3 without plus disease) or treatmentrequiring ROP, defined as Type 1 ROP (zone 1, any stage, with plus disease; zone 1, stage 3 without plus disease; or zone 2, stage 2 or 3, with plus disease) or threshold ROP (at least 5 contiguous or 8 non-contiguous clock hours of stage 3 in zone 1 or 2, with plus disease)* in 35-37 week postmenstrual infants.	Identical

Feature	Subject Device RetCam Envision	PREDICATE DEVICE RetCam Ophthalmic Imaging Systems (K182263)	Similarities or Differences
Principle of Operation	Digital camera in a handpiece with multiple field of view lenses used to capture color ophthalmic images. An on board computer is used to store, view, retrieve, and export the digital ophthalmic images. A White or RGB, and Blue LED light source is used in all RetCam configurations to provide illumination to the eye through the handpiece.	Digital camera in a handpiece with multiple field of view lenses used to capture color ophthalmic images. An on board computer (RetCam 3) or laptop computer (RetCam Shuttle and RetCam Portable) is used to store, view, retrieve, and export the digital ophthalmic images. A standard Halogen light source is used in all RetCam configurations to provide illumination to the eye through the handpiece.	On board computer only Light source replaced with LED. Light safety meets requirements of ISO 15004-2:2007 and ANSI Z80.36:2016
Technological Characteristics			
Imaging Options	Color, Red Free, Black & White	Color, Red Free, Black & White	Same
Eye contact materials	Biocompatible, coated glass	Biocompatible, coated glass	Identical eye contact material
Lenses	Coated glass with 130 degree common fields of view	Coated glass with 130, 120, 80, 30 degree common fields of view lens options)	Same lens materials and max (130 Deg) Field of view.
Portrait lens (for external non-contact imaging	Yes	Yes	Same
Detachable Lenses	Detachable and Interchangeable	Detachable and Interchangeable	Same

Feature	Subject Device RetCam Envision	PREDICATE DEVICE RetCam Ophthalmic Imaging Systems (K182263)	Similarities or Differences
Lens Disinfection Type	Supports High Level Disinfection	Supports High Level Disinfection	Same
Handpiece & Lens	Handpiece 0.8lbx Lens 0.2lbs Combined 1lbs (excluding cable weight).	Combined Handpiece and lens weight 2.7 lbs (Excludig cable)	Lighter, improved over predicate.
Camera Specifications			
Camera sensor type	3 CMOS Chip, Color	1 CMOS Chip; color	Similar with improved technology over predicate
Effective Pixels/Resolution	1920x1080 pixels Scaled to 4:3 780x600 pixels Video: 30 frames per second	1600x1200 pixels Scaled to 4:3 780x600 pixels Video: 14 frames per second	Same resulting image size 780x600 improved technology over predicate
Interface connection to the RetCam computer	USB 3	USB 3	Same as predicate
Ambient operating temperature	50º F to 95º F (10º C to 35º C)	0-50°C/32-122 °F	
Image sensor height	1/2.9" 2.1MP	1/2"	Similar

Feature	Subject Device RetCam Envision	PREDICATE DEVICE RetCam Ophthalmic Imaging Systems (K182263)	Similarities or Differences
Required power	Ratings: 100-240 V~, 50/60 Hz, 400 VA Fuses: 3AG 6.3A 250V slo-blo 5 x 20 mm Power consumption: 400 W maximum with all options Detachable hospital-grade power cord	100-2**********40V 50/60Hz	
Light Source	White, and Blue LED	White and Blue Halogen	Improvement over predicate, complies with ISO and ANSI safety standards
System Cart	Height adjustable Includes integrated device controls	Fixed height Includes integrated device controls	Improved over predicate
Foot switch for focus, brightness and image capture	Yes	Yes	Identical
DICOM	Yes	Yes	Same
Backup Battery	Lithium Ion	Lead Acid	Improved technology

The RetCam Envision System and the predicate device RetCam Opthamlic Imaging System are equivalent in features and technical characteristics. There are no major differences that significantly alter the intended use or raise new issues of safety or effectiveness.

Brief Summary of Performance Testing

Electrical Safety

The RetCam Envision was verified for performance in accordance with the following standard:

- *IEC 60601-1-6: 2010, Am1: 2013, Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability,* and IEC *62366: 2007, Am1: 2014, Medical devices - Application of usability engineering to medical devices*

Electromagnetic Compatibility

The RetCam Envision was verified for performance in accordance with the following standard:

- *IEC 60601-1-2 Edition4.0: 2014-02, Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility – Requirements and tests.*

Packaging and Handling Verification

The packaged Natus RetCam Envision components have successfully passed packaging and handling verification per ISTA-2B: Packaged Products weighing over 150 lbs (68 kg).

Performance Testing – Bench Verification & Validation

The Natus RetCam Envision has successfully passed performance verification and validation in accordance with internal requirements and specifications at the system level.

The Bench testing verification and validation was performed to confirm

Device meets the functional and performance characteristics.

Additionally, the modified/subject RetCam Ophthalmic Imaging Systems have been tested internally and met defined acceptance criteria. The tests included:

- Image Comparison Test
- Optics verification and Validation Test
- Software Test
- Mechanical design Test
- Light Safety Test
- EMC and Electrical Safety Test
- Biocompatability Test
- Packaging ISTA Test

Results indicate that the RetCam Envision system complies with its predetermined specifications and the applicable standards.

Conclusions

The substantial equivalence of the RetCam Envision with RetCam 3 (K182263) was demonstrated by testing in compliance with the Design Control process. The intended use and technology of the RetCam Envision is similar to that of the predicate device(s). Verification and Validation were performed to ensure no new questions of safety or effectiveness are raised. The results of these activities demonstrate that the RetCam Envision is as safe, as effective, and performs as well as or better than the predicate device.