September 7, 2018

Natus Medical Incorporated
Brian Ackley
Manager, Quality and Regulatory Affairs
1183 Quarry Lane, Suite A
Pleasanton, CA 94566

Re: K182263
Trade/Device Name: RetCam 3; RetCam Shuttle; RetCam Portable
Regulation Number: 21 CFR 886.1120
Regulation Name: Ophthalmic camera
Regulatory Class: Class II
Product Code: HKI
Dated: August 16, 2018
Received: August 22, 2018

Dear Brian Ackley:

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 -A

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)*
K182263

Device Name
RetCam Ophthalmic Imaging Systems
RetCam 3 Ophthalmic Imaging System
RetCam Shuttle Ophthalmic Imaging System, RetCam Portable Ophthalmic Imaging System

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.

510(k) Summary
RetCam Ophthalmic Imaging Systems

Submitter Name: **Natus Medical Inc.**

Submitter Address: **1183 Quarry Lane, Suite A**
Pleasanton, CA 94566 USA

Contact Person: **Brian Ackley**

Phone Number: **925-201-1680**

Fax Number: **925-251-0078**

Date Prepared: **August 16, 2018**

Device Trade Names: **RetCam Ophthalmic Imaging Systems**
RetCam 3 Ophthalmic Imaging System
RetCam Shuttle Ophthalmic Imaging System
RetCam Portable Ophthalmic Imaging System

Device Common Name: Ophthalmic Imaging System

Product Code: HKI

Classification: Ophthalmic Imaging Systems have been classified as Class II according to 21 C.F.R. § 886.1120

Predicate Device: RetCam Ophthalmic Imaging Systems, K090326

Device Description:

RetCam Ophthalmic Imaging Systems utilize a digital camera in a handpiece (with multiple field of view lenses) to capture color ophthalmic images including retinal, corneal, and external images. An on board computer (RetCam 3 Ophthalmic Imaging System) or laptop computer (RetCam Shuttle Ophthalmic Imaging System and RetCam Portable Ophthalmic Imaging System) is used to store, view, retrieve, and export the digital ophthalmic images. A standard Halogen light source is used in all RetCam Ophthalmic Imaging Systems to provide illumination to the eye through the handpiece. An optional Fluorescein light source is also available on the RetCam 3 Ophthalmic Imaging System.

Light intensity, camera focus, and image capture are controlled by the use of the footswitch on all RetCam Ophthalmic Imaging Systems and can also be controlled by a keyboard on the RetCam 3 Ophthalmic Imaging System console. A console monitor is provided with the RetCam 3 Ophthalmic Imaging System for viewing images. The laptop monitor is used with the RetCam Shuttle Ophthalmic Imaging System and RetCam Portable Ophthalmic Imaging System. Proprietary software is installed on the computers to capture, store, view, retrieve, and export ophthalmic images.

Intended Use/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 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.

Performance Data:

The modified/subject devices are modified versions of the previously cleared RetCam Ophthalmic Imaging Systems cleared under K090326 (predicate).

The modifications were made to upgrade the camera (due to obsolescence), add DICOM communication features, and update the software to support the modifications. The fundamental scientific technology and indications for use for the modified/subject devices are unchanged.

The modified/subject RetCam Ophthalmic Imaging Systems have been tested and found to comply with the following recognized consensus standards:

- IEC 60601-1:2005, (MOD) Medical electrical equipment - Part 1: General requirements for basic safety and essential performance

- IEC 60601-1-2:2007/(R) 2012 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests

- DICOM (Digital Imaging and Communications in Medicine) –Developed by the American College of Radiology and the National Electrical Manufacturers Association. NEMA PS 3.1-3.20 (2016)

Natus Medical Inc. followed the FDA guidance document, "Guidance for the content of Premarket Submissions for Software Contained in Medical Devices May 11, 2005," to classify the RetCam Ophthalmic Imaging Systems software as a "moderate level of concern." The software was verified and validated, and the software verification and validation documents were prepared and presented in accordance with FDA's guidance document.
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
-ISTA Test

Substantial Equivalence:

The modified/subject RetCam Ophthalmic Imaging Systems:
RetCam 3 Ophthalmic Imaging System,
RetCam Shuttle Ophthalmic Imaging System, and
RetCam Portable Ophthalmic Imaging System

have the following similarities to the predicate RetCam Ophthalmic Imaging Systems cleared under 510(k) K090326:

- *have the same indications for use,*
- *has the same fundamental scientific technology*
- *uses the same operating principle*
- *incorporates the same basic design, and*
- *incorporates the same materials*

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Feature	Modified/Subject DEVICE RetCam Ophthalmic Imaging Systems	PREDICATE DEVICE RetCam Ophthalmic Imaging Systems (K090326)	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 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.	-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 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.	No changes

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Feature	Modified/Subject DEVICE RetCam Ophthalmic Imaging Systems	PREDICATE DEVICE RetCam Ophthalmic Imaging Systems (K090326)	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 (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.	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.	No changes
Technological Characteristics			
Eye contact materials	Biocompatible	Biocompatible	No changes
Lenses	Coated glass	Coated glass	No changes
Handpiece Assembly Shell design	Plastic Shell -2.7 lbs	Plastic Shell -2.7 lbs	No changes
Portable Console			
-RetCam 3	Plastic Housing -197 lbs	Plastic Housing -197 lbs	No changes
-RetCam Shuttle	Aluminum Housing -65 lbs	Aluminum Housing -65 lbs	No changes
-RetCam Portable	Plastic Carrying Case -36 lbs or Carrying case -23 lbs	Plastic Carrying Case -36 lbs or Carrying case -23 lbs	No changes

In summary, the modified/subject RetCam Ophthalmic Imaging Systems:

RetCam 3 Ophthalmic Imaging System,
RetCam Shuttle Ophthalmic Imaging System, and
RetCam Portable Ophthalmic Imaging System

described in this submission are substantially equivalent to the predicate device.