June 8, 2018

Next Sight srl
Arianna Dalla Bá
Quality and Regulatory Affairs Specialist
Via IV Novembre 6/E
Limena (Padova), 35010 IT

Re: K180306
Trade/Device Name: Nexy
Regulation Number: 21 CFR 886.1120
Regulation Name: Ophthalmic Camera
Regulatory Class: Class II
Product Code: HKI
Dated: March 13, 2018
Received: March 15, 2018

Dear Arianna Dalla Bá:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); 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,

Denise L. Hampton -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)*
K180306

Device Name
Nexy

Indications for Use *(Describe)*
Nexy device is an automatic eye-fundus camera intended for taking digital images of a human retina without the use of a mydriatic agent.

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."

next sight
SEEN THE DIFFERENCE ?
NEXT SIGHT SRL
WWW.NEXTSIGHT.INFO
Headquarters
VIA IV NOVEMBRE, 6/E
35010 LIMENA (PD) - ITALY
TEL. +39 049 - 76 99 33

510(K) Summary K180306

GENERAL INFORMATION:

Company Name: Next Sight srl

Address: Via IV Novembre 6/E
35010 - Limena (Padova)
Italy

Phone: +39049769933

Contact Person: Arianna Dalla Bà

Title: Quality and Regulatory Affairs Specialist

Address: Via IV Novembre 6/E
35010 - Limena (Padova)
Italy

Email: arianna.dallaba@nextsight.info

Phone: +39049769933

Date Prepared: January 31, 2018

DEVICE IDENTIFICATION:

Trade Name: Nexy

Generic Device Name: Camera, Ophthalmic, Ac-Powered

Review Panel: Ophthalmic

Classification: Class II

Regulation Number: 21 CFR 886.1120

Product Code: HKI

Headquarters
VIA IV NOVEMBRE, 6/E
35010 LIMENA (PD) - ITALY
TEL. +39 049 - 76 99 33

Device Description:

The Nexy medical device is an automatic eye-fundus camera without the use of a mydriatic agent, designed to take color photos of the retinal fundus with a 45° field.

The device consists of two fundamental components: the eye-fundus camera and the tablet which represents the user interface where running a dedicated software application.

The instrument body includes: optical head, forehead and cheekbones rests and a base. The device is provided also with a front lens cap, a power cord and AC/DC adaptor.

Through the tablet, the user starts the automatic examination that provides as output the photo of the patient's retina saved in the internal database of the device in JPEG format.

The device can be used in a hospital environment, public and private health clinics and in public and private environments where eye or systemic diseases are screened.

The device must be used by medical personnel in some cases assisted by health professionals and/or optometry professionals. Users must be adequately trained in the use of the device and informed about the risks and side effects as well as being in possession of the qualifications required by law.

Indications For Use:

Nexy device is an automatic eye-fundus camera intended for taking digital images of a human retina without the use of a mydriatic agent.

Headquarters
VIA IV NOVEMBRE, 6/E
35010 LIMENA (PD) - ITALY
TEL. +39 049 - 76 99 33

Identification of predicate devices:

The predicate devices selected for comparison with the subject device are identified as follows:

Predicate Device	**510(k) Holder Name**	**510(K) no.**	**Date cleared**
Digital Retinography System DRS	CenterVue	K101935	27 October 2010
MiiS Horus Scope DEC 100	Medimaging Integrated Solution Inc. (MiiS)	K120982	28 September 2012

Bench tests

As the predicate device DRS (K101935), Nexy device complies with the following standards:

- IEC 60601-1:2005;
- IEC 60601-1-2:2007;
- ISO 10940-2:2009;
- ISO 15004-2 2007.

Nexy complies also with the following standards:

- ISO 15004-1:2006
- ISO 14971: 2012
- ISO 62366:2007
- ISO 62304: 2006
- DICOM standard

Predicate Device comparison

Table 1 provides a comparison between the subject device and the predicate devices.

Table 1 - Predicate device comparison table			
ATTRIBUTE / CHARACTERISTICS	**Nexy Subject Device**	**Digital Retinography System DRS Predicate Device PD1**	**MiiS Horus Scope DEC 100 Predicate Device PD2**
Device Name	Nexy	Digital Retinography System DRS	MiiS Horus Scope DEC 100
Comparison: Not Applicable			
Device Manufacturer	Next Sight srl	CentreVue	Medimaging Integrated Solution Inc. (MiiS)
Comparison: Not Applicable			
FDA Product Code	HKI	HKI	HKI
Comparison: Both predicate devices PD1 and PD2 have the same FDA product code as subject device.			
510k reference	K180306	K101935	K120982
Comparison: Not Applicable			
FDA Classification Name	Camera, Ophthalmic, Ac-Powered	Camera, Ophthalmic, Ac-Powered	Camera, Ophthalmic, Ac-Powered
Comparison: Both predicate devices PD1 and PD2 have the same FDA Classification Name as subject device.			
Classification	II	II	II
Comparison: Both predicate devices PD1 and PD2 have the same Classification as subject device.			
FDA Regulation Number	886.1120	886.1120	886.1120
Comparison: Both predicate devices PD1 and PD2 have the same FDA Regulation Number as subject device.			
Type of device	Fundus non-mydriatic camera	Fundus non-mydriatic camera	Fundus non-mydriatic camera
Comparison: Both predicate devices PD1 and PD2 have the same Type of device as subject device.			
Indication for Use	Nexy device is an automatic eye-fundus camera intended for taking digital images of a human retina without the use of a mydriatic agent.	The CenterVue Digital Retinography System DRS is intended for taking digital images of a human retina without the use of a mydriatic agent.	MiiS Horus Scope DEC 100 is a digital hand-held eye-fundus camera used to record digital photographs and video of fundus of the human eye and surrounding area.
Comparison: Predicate device PD1 has the same Indication for Use as subject device. The predicate device PD2 has similar Indication for Use to the subject device.			

Table 1 - Predicate device comparison table			
ATTRIBUTE / CHARACTERISTICS	**Nexy Subject Device**	**Digital Retinography System DRS Predicate Device PD1**	**MiiS Horus Scope DEC 100 Predicate Device PD2**
Treatable areas	Eyes	Eyes	Eyes
Comparison: Both predicate devices PD1 and PD2 have the same treatable areas as subject device.			
Target Population	All population with some exceptions: the device cannot be used on children and in any case on minors, without the assistance of an adult.	Not Available	Not Available
Comparison: This information is not available in the competitors' documentation.			
Alignment and examination	Automatic – the device automatically aligns to the center of the pupil prior to autofocusing and capture.	Automatic – the DRS device automatically aligns to the center of the pupil prior to autofocusing and capture.	Manual – MiiS Horus Scope DEC 100 is a digital hand-held eye-fundus camera.
Comparison: Predicate device PD1 has the same alignment and examination as subject device. The alignment of the predicate device PD2 is different from the subject device.			
Field of horizontal vision	45°	45°	40°
Field of vertical vision	45°	40°	40°
Comparison: Field of view represents the portion of the field of vision of the retina that can be framed with the device. The predicate device PD1 as the same filed of horizontal vision as the subjected device. The Field of horizontal vision of the predicate device PD2 is different from the subject device.			
Minimum pupil size	3.8mm	4mm	3.5mm
Comparison: The minimum pupil size parameter represents the size of the smallest pupil in order to take the exam. Both predicate devices PD1 and PD2 have similar minimum pupil size as subject device.			
Image sensor	CMOS	CMOS	CMOS
Comparison: Both predicate devices PD1 and PD2 have the same image sensor as subject device.			

Table 1 - Predicate device comparison table			
ATTRIBUTE / CHARACTERISTICS	**Nexy Subject Device**	**Digital Retinography System DRS Predicate Device PD1**	**MiiS Horus Scope DEC 100 Predicate Device PD2**
Sensor size	2.1 Mpixel	5 Mpixel	2 Mpixel
Comparison: Predicate device PD2 has a similar sensor size as subject device. The sensor size of the predicate device PD1 is different from the subject device.			
Image Format	JPEG, DICOM	JPEG, DICOM	JPEG and Video (AVI)
Comparison: Predicate device PD1 has the same image format as subject device. The image format of the predicate device PD2 is the same for JPEG and it is different for AVI from the subject device.			
Resolution on retina	14 µm	15 µm	This information is not available for this predicate device.
Comparison: Predicate device PD1 has similar resolution on retina as subject device. This parameter indicates the level of distinguishable detail, Nexy resolution on retina differs by 1 µm from the predicate device PD1.			
Light source	LEDs	LEDs	LEDs
Comparison: Both predicate devices PD1 and PD2 have the same light source as subject device.			
Type of fixation light	Green and continuous (during the exam time)	Green and continuous (during the exam time)	Not Applicable
Comparison: Both predicate devices PD1 and PD2 have the same type fixation light as subject device.			
Focus on the retina – type of light	IR (infrared) LEDs and continuous source (during the focusing time)	IR (infrared) LEDs and continuous source (during the focusing time)	This information is not available for this predicate device.
Comparison: Both predicate devices PD1 and PD2 use the infrared LEDs to perform the focus on the retina.			
Type of flash	White LEDs in the visible range and pulsed (duration less than 50ms) with annular shape on the cornea.	White LEDs in the visible range and pulsed (duration less than 50ms) with annular shape on the cornea.	This information is not available for this predicate device.
Comparison: Both predicate devices PD1 and PD2 use and comparable (color, technology, shape on the cornea type of light to flash the retina.			
Exposure conditions	In accordance to the flash duration time.	In accordance to the flash duration time.	This information is not available for this predicate device.
Comparison: Both exposure conditions of predicate devices PD1 and PD2 are in accordance to the flash duration time.			
Light feature	Polarized	Not polarized	Polarized
Comparison: Predicate devices PD2 has the same light source as subject device. It is different for			

Table 1 - Predicate device comparison table			
ATTRIBUTE / CHARACTERISTICS	**Nexy Subject Device**	**Digital Retinography System DRS Predicate Device PD1**	**MiiS Horus Scope DEC 100 Predicate Device PD2**
the predicate device PD2.			
Diopter adjustment	+15D / -15D	+15D / -15D	+20D / -20D
Comparison: Predicate devices PD1 has the same diopter adjustment as subject device. It is different for the predicate device PD2.			
Number of Fixings	7	7	Not Applicable
Comparison: Predicate devices PD1 has the same Number of Fixings as subject device.			
Fixation target	Internal LEDs	Internal LEDs	Not Applicable
Comparison: Predicate devices PD1 has the same Fixation target as subject device.			
DICOM standard compliance	Yes	Yes	This information is not available for this predicate device.
Comparison: Predicate devices PD1 complies to DICOM standard as subject device.			
Performance Standard Compliance	Nexy device complies with the following standards: • IEC 60601-1:2005; • IEC 60601-1-2:2007; • ISO 10940-2:2009; • ISO 15004-2 2007. Nexy complies also with the following standards: • ISO 15004-1:2006 • ISO 14971: 2012 • ISO 62366:2007 • ISO 62304: 2006	The DRS complies with the following standards: IEC 60601-1:2005; IEC 60601-1-2:2007; ISO 10940-2:2009; ISO 15004-2 2007.	This information is not available for this predicate device.
Comparison: Predicate devices PD1 complies to the same standards as subject device. Furthermore the subject device complies with other standards.			

TESTING IN SUPPORT OF SUBSTANTIAL EQUIVALENCE DETERMINATION

All necessary bench testing was conducted on Nexy to support a determination of substantial equivalence to the predicate devices. The tests performed include:

- Ophthalmic Testing per ISO 15004-1, and ISO15004-2
- Ophthalmic Testing about Fundus Cameras per ISO 10940 Ophthalmic Instruments -- Fundus Cameras
- Software Verification and Validation per AAMI/ANSI/IEC 62304 The software of this device was considered as a "Moderate" level of concern based on the FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices" issued on: May 11, 2005
- Electrical Safety Testing per IEC60601-1 and Electromagnetic Compatibility Testing per IEC60601-1-2.

The collective performance testing demonstrates that the Nexy device does not raise any new questions of safety or effectiveness when compared to the predicate devices. The results of the performance testing demonstrate that the Nexy device performs as intended and does not raise any new questions of safety or effectiveness.

Conclusion

None of the differences highlighted in the Table 1 introduce new issues of safety and effectiveness compared to predicate devices.
The remaining technical aspects of the Nexy device compared with the predicate devices are identical or very similar.

Based on the information contained in this submission, it is concluded that the Nexy device is substantially equivalent to the identified predicate devices already in commerce within the USA and that any differences that do exist have no effect on the safety and effectiveness of the device.