January 29, 2021

Luneau Technology Operations
Yossi Constantinis
Group Regulatory Affairs & Quality Manager
2 rue Roger Bonnet
Pont-de-l'Arche, Rouen 27340
France

Re: K202221
Trade/Device Name: VX650
Regulation Number: 21 CFR 886.1930
Regulation Name: Tonometer and Accessories
Regulatory Class: Class II
Product Code: HKX, HKI, MXK
Dated: December 21, 2020
Received: December 28, 2020

Dear Yossi Constantinis:

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,

for 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)*
K202221

Device Name
VX650

Indications for Use *(Describe)*
The VX650 is a multi-function diagnostic device combining wavefront aberometer, corneal topographer, retro-illuminator, tonometer and pachymeter, indicated for:

- Measuring the refraction of the eye giving both lower and higher order aberrations
- Measuring the shape of the cornea
- Retro-illumination imaging of the eye
- Measuring the intraocular pressure without contacting the eye for glaucoma evaluation
- Photographing the eye and taking images of the eye to evaluate the thickness of the central cornea
- Full cornea thickness map
- Scheimpflug imaging
- Anterior chamber imaging
- Pupil Image
- Image of the cornea relative to the iris
- 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.

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510(K) Summary K202221

GENERAL INFORMATION:

Company Name:	Luneau Technology Operations
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Second contact Person:	Haggai Herman General Manager Email: h.herman@luneautech.com
Address:	2 rue Roger Bonnet, 27340 Pont-de-l'Arche France
Date Prepared:	August 3rd, 2020

DEVICE IDENTIFICATION:

Trade Name:	VX650
Generic Device Name:	Tonometer, Ac-Powered
Review Panel:	Ophthalmic
Classification:	Class II
Regulation Number:	21 CFR 886.1930
Product Code:	HKX

Subsequent product codes, based on other device functions in Class II:	HKI Camera, Ophthalmic, Ac-Powered MXK Device, Analysis, Anterior Segment

Device Description:

The VX650 is based on the VX130 (already cleared 510(k), number K162067) which is a combined wavefront aberrometer, corneal topographer, Scheimpflug pachymeter, non-contact tonometer and cataract screening device in a single platform that contains five different measurement units. The VX650 also contains a non-mydriatic fundus camera for retinal photography. The wavefront aberrometer uses the Shack-Hartmann principle and is used as an advanced autorefractometer that measures both lower and higher order aberrations of the refraction of the eye.

The corneal topographer uses a Placido disk to measure keratometry and the detailed shape of the cornea. The Scheimpflug pachymeter measures the thickness of the central cornea by illuminating it with a slit of light and photographing it using the Scheimpflug technique, there is also a scanning mode that allows measurement of the whole corneal surface and can provide detailed tomography maps of both corneal surfaces and the corneal thickness.

An air puff non-contact tonometer is included for measurement of the intraocular pressure and retro illumination is present for cataract screening.

The fundus camera contains an infra-red LED for alignment and focusing and a white LED flash for the photography to give colour images. The fundus image covers an angle of 45° on the retina so a regular image will contain both the macula and the optic nerve. The fundus camera also has a seven-position fixation target to increase the field of view as the patient can fixate in different directions.

The device is fully automated and a number of different measurements can be performed by a single command including alignment and focusing. The fundus imaging function is also fully automatic including automatic alignment, focusing and image capture.

Indications For Use:

The VX650 is a multi-function diagnostic device combining wavefront aberometer, corneal topographer, retro-illuminator, tonometer and pachymeter, indicated for:

- Measuring the refraction of the eye giving both lower and higher order aberrations
- Measuring the shape of the cornea
- Retro-illumination imaging of the eye
- Measuring the intraocular pressure without contacting the eye for glaucoma evaluation
- Photographing the eye and taking images of the eye to evaluate the thickness of the central cornea
- Full cornea thickness map
- Scheimpflug imaging
- Anterior chamber imaging
- Pupil Image
- Image of the cornea relative to the iris
- Automatic eye-fundus camera intended for taking digital images of a human retina without the use of a mydriatic agent

Identification of predicate devices:

The subject device is substantially equivalent to the following:

Primary predicate Device	**510(k) Holder**	**510(k) no.**	**Date cleared**
VX130	Luneau	K162067	24 April 2017

The primary predicate refers to the one with indications for use and technological characteristics most similar to the subject device.

Additional predicate devices related to fundus camera module	**510(k) Holder**	**510(k) no.**	**Date cleared**
Nexy	Next Sight	K180306	8 June 2018
CenterVue Digital Retinography System DRS	CenterVue	K101935	27 October 2010

Bench tests

As the predicate device VX130 (K162067), VX650 device complies with the following standards:

- ISO 14971 Third Edtion 2019-12
- AAMI ANSI ES60601- 1:2005/(R)2012 And A1:2012
- IEC 60601-1-2 Edition 4.0 2014-02
- ISO 15004-1 First edition 2006-06-01
- ISO 10940 Second edition 2009-08-01
- IEC 62471 First edition 2006-07
- IEC 60825-1 Edition 2.0 2007-03
- ISO 10993-1 Fourth edition 2009-10-15
- IEC 62366-1 Edition 1.0 2015-02
- IEC 60601-1-6 Edition 3.1 2013-10
- IEC 62304 Edition 1.1 2015-06
- ANSI Z80.36-2016 American National Standard for Ophthalmics – Light Hazard Protection for Ophthalmic Instruments

VX650 device complies also with the following standards:

- ISO 8612:2009 Ophthalmic instruments — Tonometers
- ISO 10342:2010 Ophthalmic instruments — Eye refractometers
- ISO 10343:2014 Ophthalmic instruments — Ophthalmometers
- ISO 19980:2012 Ophthalmic instruments — Corneal topographers
- ISO 24157:2008Ophthalmic optics and instruments — Reporting aberrations of the human eye

Predicate Device comparison

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

Table 1 - Predicate device comparison table with primary predicate device		
ATTRIBUTE / CHARACTERISTICS	**VX650 Subject Device**	**VX130 PD1**
Device Name	VX650	VX130
Comparison: Not Applicable		
Device Manufacturer	Luneau	Luneau
Comparison: The device manufacturer is the same.		
FDA Product Code	HKX (main and primary code)	HKX
Comparison: Predicate device PD1 has the same FDA product code as subject device.		
510k reference	K202221	K162067
Comparison: Not Applicable		
FDA Classification Name	Tonometer, Ac-Powered (for the main and primary code)	Tonometer, Ac-Powered
Comparison: Predicate device PD1 has the same FDA Classification name of submitted product.		
Classification	II	II
Comparison: Predicate device PD1 has the same FDA Classification as subject device.		
FDA Regulation Number	886.1930 (according to main code)	886.1930
Comparison: Predicate device PD1 has the same regulation number of subject device.		

Table 1 - Predicate device comparison table with primary predicate device		
ATTRIBUTE / CHARACTERISTICS	**VX650 Subject Device**	**VX130 PD1**
Indication for Use	The VX650 is a multi-function diagnostic device combining wavefront aberometer, corneal topographer, retro-illuminator, tonometer and pachymeter, indicated for: • Measuring the refraction of the eye giving both lower and higher order aberrations • Measuring the shape of the cornea • Retro-illumination imaging of the eye • Measuring the intraocular pressure without contacting the eye for glaucoma evaluation • Photographing the eye and taking images of the eye to evaluate the thickness of the central cornea • Full cornea thickness map • Scheimpflug imaging • Anterior chamber imaging • Pupil Image • Image of the cornea relative to the iris • Automatic eye-fundus camera intended for taking digital images of a human retina without the use of a mydriatic agent	The VX130 is a multi-function diagnostic device combining wavefront aberometer, corneal topographer, retro-illuminator, tonometer and pachymeter, indicated for: • Measuring the refraction of the eye giving both lower and higher order aberrations • Measurement of the shape of the cornea • Retro-illumination imaging of the eye • Measuring the intraocular pressure without contacting the eye for glaucoma evaluation • Photographing the eye and taking images of the eye to evaluate the thickness of the central cornea. • Full cornea thickness map • Scheimpflug imaging • Anterior chamber imaging • Pupil image • Image of the cornea relative to the iris
Comparison: The addition in submitted product of the last points related to the photograph of the external eye doesn't impact on performances and safety of the other functions identical to predicate device PD1; the comparison and discussion of fundus camera module has been discussed on table 2. VX650 is not different in safety or efficacy and is substantially equivalent to PD1.		
Type of device	Combination instrument	Combination instument

Table 1 - Predicate device comparison table with primary predicate device		
ATTRIBUTE / CHARACTERISTICS	**VX650 Subject Device**	**VX130 PD1**
	including fundus non-mydriatic camera	
Comparison: Predicate device PD1 is a combination instrument including multi-function. The subject device is a combination instrument including also (as an addition of predicate device PD1) a non-mydriatic fundus camera.		
Treatable areas	Eyes	Eyes
Comparison: Predicate device PD1 has the same treatable areas as subject device.		
Alignment and examination	Automatic – the device automatically aligns to the center of the pupil prior to autofocusing and capture.	Automatic – the device automatically aligns to the center of the pupil prior to autofocusing and capture.
Comparison: Predicate device PD1 has the same alignment and examination procedure as the subject device.		
General Functionalities	The general functionalities of VX650 are: • Wavefront • Keratometry • Retro illumination • Corneal topography • Tonometry • Pachymetry (single slit) • Pachymetry (multi slit) • Fundus photography	The general functionalities of VX130 are: • Wavefront • Keratometry • Retro illumination • Corneal topography • Tonometry • Pachymetry (single slit) • Pachymetry (multi slit)
Comparison: The subjected device has in addition the fundus photography, all the other functions are the same of predicate device PD1.		
Performance Standard Compliance	Complies with the following standards: • IEC 60601-1:2005 • IEC 60601-1-2:2014 • ISO 10940-2:2009 • ISO 60825-1:2014 • ISO 62471-1:2006 • ISO 8612:2010 • ISO 10342:2010 • ISO 24157:2008 • ISO 19980:2012 • ISO 10343-1:2014 • ISO 15004-2 2007 • ISO15004-1:2006 • ISO 14971: 2012 • ISO 62366:2007 • ISO 62304: 2006	Complies with the following standards: • IEC 60601-1:2005 • IEC 60601-1-2:2014 • ISO 60825-1:2014 • ISO 62471-1:2006 • ISO 8612:2010 • ISO 10342:2010 • ISO 24157:2008 • ISO 19980:2012 • ISO 10343-1:2014 • ISO 15004-2 2007 • ISO15004-1:2006 • ISO 14971: 2012 • ISO 62366:2007 • ISO 62304: 2006

Table 1 - Predicate device comparison table with primary predicate device		
ATTRIBUTE / CHARACTERISTICS	**VX650 Subject Device**	**VX130 PD1**
Comparison: Subject device and predicate device PD1 comply with relevant standards, except for ISO 10940-2:2009 that is applied specifically to VX650 since it includes fundus camera module.		

Table 2 provides a comparison between the subject device additional predicate devices related to fundus camera module.

Table 2 - Additional predicate devices related to fundus camera module			
ATTRIBUTE / CHARACTERISTICS	**VX650 Subject Device**	**Nexy Predicate Device PD2**	**Digital Retinography System DRS Predicate Device PD3**
Device Name	VX650	Nexy	Digital Retinography System DRS
Comparison: Not Applicable			
Device Manufacturer	Luneau	Next Sight srl	CenterVue
Comparison: Not Applicable			
FDA Product Code	HKX (main code); subsequent codes for class II functions are HKI and MXK	HKI	HKI
Comparison: Both predicate devices PD2 and PD3 have product code identical to one of subsequent code of subject device.			
510k reference	K202221	K180306	K101935
Comparison: Not Applicable			
FDA Classification Name	Tonometer, Ac-Powered (for the main code); for the subsequent codes: HKI Camera, Ophthalmic, Ac-Powered MXK Device, Analysis, Anterior Segment	Camera, Ophthalmic, Ac-Powered	Camera, Ophthalmic, Ac-Powered
Comparison: Both predicate devices PD2 and PD3 have the same FDA Classification name, that is the same of one of the subsequent codes of the subject device (VX650).			
Classification	II	II	II
Comparison: Both predicate devices PD2 and PD3 have the same FDA Classification as subject device.			
Type of device	Combination instument	Fundus non-mydriatic	Fundus non-mydriatic

Table 2 - Additional predicate devices related to fundus camera module			
ATTRIBUTE / CHARACTERISTICS	**VX650 Subject Device**	**Nexy Predicate Device PD2**	**Digital Retinography System DRS Predicate Device PD3**
	including fundus non-mydriatic camera	camera	camera
Comparison: Both predicate devices PD2 and PD3 are non-mydriatic fundus cameras. The subject device is a combination instrument including a non-mydriatic fundus camera module.			
Treatable areas	Eyes	Eyes	Eyes
Comparison: Both predicate devices PD2 and PD3 have the same treatable areas as subject device			
Alignment and examination	Automatic – the device automatically aligns to the center of the pupil prior to autofocusing and capture.	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.
Comparison: Both predicate devices PD2 and PD3 have the same alignment and examination procedure as the subject device.			
Field of horizontal vision	45°	45°	45°
Field of vertical vision	45°	45°	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 PD2 has the same field of view as the subject device. The field of horizontal vision of the predicate device PD3 is the same as the subject device but the vertical field is 5° smaller. Regarding the field of vertical vision, a difference of 5° degrees does not bring a point of non-substantial equivalence between the VX650 device and a predicate device, as it does not influence the intended use, the performance, the safety and effectiveness of the system.			
Minimum pupil size	3.5mm	3.8mm	4mm
Comparison: The minimum pupil size parameter represents the size of the smallest pupil that can be measured. Both predicate devices PD2 and PD3 have slightly larger minimum pupil sizes than the subject device. It does not bring a point of non-substantial equivalence between the submitted device and the predicate devices, as it does not influence the intended use, the performance, the safety and effectiveness of the system.			
Image sensor	CMOS	CMOS	CMOS
Comparison: Both predicate devices PD2 and PD3 have the same image sensor type as the subject device.			
Sensor size	6 M pixel	2.1 M pixel	5 M pixel
Comparison: Predicate device PD3 has a similar sensor resolution as the subject device. The sensor resolution of the predicate device PD2 is smaller than the subject device, the subject device therefore is slightly better.			
Resolution on	5.25 µm	14 µm	15 µm

Table 2 - Additional predicate devices related to fundus camera module			
ATTRIBUTE / CHARACTERISTICS	**VX650 Subject Device**	**Nexy Predicate Device PD2**	**Digital Retinography System DRS Predicate Device PD3**
retina			
Comparison: The subject device has better fundus resolution than the predicate devices.			
Light source	LEDs	LEDs	LEDs
Comparison: Both predicate devices PD12 and PD3 have the same light source as subject device.			
Type of fixation light	Blue and continuous (during the exam time)	Green and continuous (during the exam time)	Green and continuous (during the exam time)
Comparison: Both predicate devices PD2 and PD3 have the same type of fixation light as the subject device. The colour does not make any significant difference.			
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)	IR (infrared) LEDs and continuous source (during the focusing time)
Comparison: Both predicate devices PD2 and PD3 use infrared LEDs to perform the focus on the retina, similar to the subject device.			
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.	White LEDs in the visible range and pulsed (duration less than 50ms) with annular shape on the cornea.
Comparison: Both predicate devices PD2 and PD3 have a similar flash to the subject device (color, technology, shape on the cornea type of light to illuminate the retina).			
Performance Standard Compliance	Complies with the following standards: • IEC 60601-1:2005 • IEC 60601-1-2:2014 • ISO 10940-2:2009 • ISO 60825-1:2014 • ISO 62471-1:2006 • ISO 8612:2010 • ISO 10342:2010 • ISO 24157:2008 • ISO 19980:2012 • ISO 10343-1:2014 • ISO 15004-2 2007 • ISO15004-1:2006 • ISO 14971: 2012 • ISO 62366:2007 • ISO 62304: 2006	Complies with the following standards: • IEC 60601-1:2005 • IEC 60601-1-2:2007 • ISO 10940-2:2009 • ISO 15004-2 2007 • ISO 15004-1:2006 • ISO 14971: 2012 • ISO 62366:2007 • ISO 62304: 2006	Complies with the following standards: • IEC 60601-1:2005 • IEC 60601-1-2:2007 • ISO 10940-2:2009 • ISO 15004-2 2007
Comparison:			

Table 2 - Additional predicate devices related to fundus camera module			
ATTRIBUTE / CHARACTERISTICS	**VX650 Subject Device**	**Nexy Predicate Device PD2**	**Digital Retinography System DRS Predicate Device PD3**
Subject device and predicate devices PD2 and PD3 comply with relevant standards; the subject device includes also the applicability of additional standards for the other functions, as described above on Table 1.			

TESTING IN SUPPORT OF SUBSTANTIAL EQUIVALENCE DETERMINATION

All necessary bench testing was conducted on VX650 to support a determination of substantial equivalence to the primary predicate device and to additional predicate device for fundus camera module. The tests performed include also:

- 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 VX650 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 VX650 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 and 2 introduce new issues of safety and effectiveness compared to predicate devices.

The remaining technical aspects (fundus camera module) of the VX650 compared with the additional predicate devices are considered very similar.

Based on the information contained in this submission, it is concluded that the VX650 device is substantially equivalent to the identified primary predicate device already in commerce within the USA and that any differences that do exist have no effect on the safety and effectiveness of the device.