DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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June 1, 2015

LUNEAU SAS
Ms. Isabelle Durand
Quality/RA Manager
1 avenue de Malaguet
CS 9001 Prunay le Gillon
28360 Gellainville Cedex France

Re: K143086
Trade/Device Name: VX120 Ophthalmic Diagnostic Device
Regulation Number: 21 CFR 886.1930
Regulation Name: Ophthalmic Diagnostic Device
Regulatory Class: Class II
Product Code: HKX
Dated: April 30, 2015
Received: May 1, 2015

Dear Ms. Durand:

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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Kesia Y. Alexander -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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K143086

Device Name
VX120

Indications for Use *(Describe)*
The VX120 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 comea
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 cornea.

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

VX120 ophthalmic diagnostic device

May 19th, 2015

I. SUBMITTER

LUNEAU SAS
1 avenue de Malaguet
28360 Prunay le Gillon
France
Phone : +33 (0)2 37 25 25 25
Fax: +33(0)2 37 25 75 99

Contact person: Isabelle Durand

II. DEVICE

Name of Device: VX120
Common name: Ophthalmic diagnostic device
Classification: tonometer , AC powered
Regulatory class: II
Product code: HKX
Regulation number: 886.1930

III. PREDICATE DEVICES

The VX120 is claimed to be substantially equivalent to the following currently marketed devices:
Keeler Pulsair Desktop Tonometer
Manufacturer: Keeler Ltd .
FDA K093298 issued Dec 10, 2010.
Product code: HKX

Pentacam, Scheimplug camera
Manufacturer: Oculus Optikgeraete GmbH, Germany
FDA K030719 issued Sept 16, 2003.
Product code: MXK

The VX120 is equivalent for other functions not subject to 510(k) to the following device:
VX110: combined wave front aberrometer, corneal topographer and retroillumination device.
Manufacturer: Luneau SAS
510(k) exempt, regulation number 886.1760
Product code: HKO

IV. DEVICE DESCRIPTION

The VX120 is a multifunctional ophthalmic diagnostic device.

The VX120 combined wavefront aberrometer, corneal topographer, retro illumination device, Scheimpflug pachymeter, and non-contact tonometer is a single platform that contains five different measurement units.

The wavefront aberrometer works on 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.

Retro illumination is used to image ocular opacities.

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.
An air puff non-contact tonometer is included for measurement of the intraocular pressure.
The device is fully automated and a number of different measurements can be performed by a single command including alignment and focusing.

V. INDICATIONS FOR USE

The VX120 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 cornea.

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VI. COMPARISON OF INTENDED USE AND TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICES

1. The Tonometer function of the VX120 is claimed to be substantially equivalent to the following currently marketed device: Keeler Pulsair Desktop Tonometer,Keeler Ltd . UK, K093298
   The tonometer function of VX120 and the Pulsair Desktop Tonometer have the same intended use, they are indicated to be used to aid with the glaucoma evaluation.
   They measure intraocular pressure without contact with the eye by applying an air puff to the eye. VX120, is not indicated in patients with less than 3 diopters of corneal astigmatism. The maximum IOP that can be measured with this device is 44 mmHg.

Comparison of non-contact tonometer Technological characteristics		
	Pulsair tonometer	**Vx120**
Type	Air Puff Non Contact Tonometer	Air Puff Non Contact Tonometer
Illumination	720nm 1W LED	720nm 1W LED
Measurement Range	5 to 50mmHg	7 to 44mmHg
Displayed Scale	Direct in mmHg	Direct in mmHg
Air Puff Generation	Vacuum Diaphragm Pump (Type: NPK04)	Vacuum Diaphragm Pump (Type: NPK04)
Accuracy	±2 mmHg	±2 mmHg
Pressure of Air Expelled from Tonometer	30mmHg & 70mmHg	30mmHg & 70mmHg
Power Supply	100-240 V AC, 50/60 Hz, 400 W	100-240 V AC, 50/60 Hz, 400 W
Measurement Method	Opto Electronic	Opto Electronic
User Interface	Factory Set / User Changeable	Factory Set / User Changeable
Printer	Built in	Built in
Data Display	Single line 16 characters LCD	Full Colour LCD
Data storage capability		Results and patient information
Mounting Options	Desk mounted	Desk mounted
Dimensions (W×L×H)	450mmx435mmx245mm	312mm × 530mm × 570mm
Weight	16 kg	25 kg
Software Level of Concern	Moderate	Moderate
Reliance on Standards	ISO8612:2001	Full clinical trial conducted in 2014 to ISO18612:2010

2. The pachymeter function of the VX120 is claimed to be substantially equivalent to the following currently marketed device: Pentacam Scheimpflug Camera, OCULUS Optikgeraete GmbH, Germany; K 030719

   The pachymeter function of the VX120 has the same intended use than Pentacam for photographing the eye and taking images of the anterior segment of the eye to evaluate the thickness of the cornea.

The Pentacam and the VX120 systems are based on the Scheimpflug Principle for slit image photography. The measurement systems use blue light (UV-free) through a slit to illuminate the eye, and a Camera for photography. The devices take a series of images of the anterior segment of the eye and analyse the images, selected by the software.

Comparison of pachymeter technological characteristics		
	Pentacam	**VX120**
Manufacturer	Oculus Optigerate GmbH	Luneau
Measurement principle	Scheimpflug principle for slit image photography	Scheimpflug principle for slit image photography
Observation illumination	Infrared LED 800nm for pupil illumination	Infrared LED 880nm for pupil and corneal illumination
Flash output illumination	Blue LED light (UV free) 475nm, max 2.5W power input	Blue LED light (UV free) 455nm, max 1.2W power input
Camera	CCD camera	CMOS camera
Display	Data digital, displayed on a CPU	Data digital, displayed on LCD screen
Image resolution	800 × 600 pixels	1600 × 1000 pixels
Measuring points	500 per image	300 per surface (2 surfaces per image)
Image size	5.6× 4.5 mm	3.5 × 2.2 mm
Photographic range	0° to 360°	Fixed slit position 180°
Photographic series	1 to 50 images	5 images
Exposure control	Fixed during calibration, max 2.5Wsec power input	Fixed during calibration, max 50mW for 300 mS (0.015Wsec) power input
Slit length	14mm fixed	8mm fixed
Power supply	External 110/220 VAC, 50/60Hz	100-240 VAC, 50/60Hz
Power consumption	50VA	400W
Power requirement	25VDC, 2A / 5VDC, 2A	
Weight	9kg	25 kg

The systems contain

- similar optical systems,
- a similar source of illumination for observation and photography,
- a camera as a photographic medium,

Both systems use the same device features like a

- head stabilizing device
- fixation target
- alignment control mechanism.

VII. PERFORMANCE DATA

The following performance data were provided in support of the substantial equivalence determination:

1. Electrical safety and EMC testing were conducted on the VX120. The device complies with IEC60601-1:2006, and the IEC60601-1-2 for EMC.
2. Software verification and validation testing was done according to IEC62304.
3. Risk management: VX120 was evaluated according to ISO14971: 2009. All risks have been reduced to safe levels thus there is no conflict between risk and benefit.
4. Tests for ophthalmic products: VX120 was evaluated in accordance with ISO15004-1:2009 and ISO15004-2:2007 standards and was found to meet all requirements of the standards. For optical hazards, VX120 was evaluated in accordance with IEC60825-1: 2008: the result is VX120 is laser class 1.
5. Tests for tonometers:
    a. Bench testing:

    Accuracy and repetability tests have been performed ; the accuracy is equivalent to ±2mmHg or better and the standard deviation is ±1.2 mmHg or better.
    b. Clinical evaluation: VX120 was evaluated in accordance with ISO8612:2010 and ANSI Z80.10-2009 and was found to meet all requirements of the standards if eyes with astigmatism >3mm are excluded.
6. Tests for pachymetry:

    A comparison study of Central Corneal Thickness measurements done with VX120 and Pentacam shows that there was no significant statistical difference between measurements of CCT with VX120 and the Pentacam.

VIII. CONCLUSIONS

The VX120 is substantially equivalent to the predicate devices for its tonometry and pachymetry functions. The VX120 has the same intended use, technological characteristics, and principles of operation as its predicate devices.
The VX120 other functions are equivalent to VX110
The technological differences between the VX120 and its predicates raise no new issues of safety and effectiveness. Performance data demonstrates that the VX120 is as safe and effective as the predicate devices for tonometry and pachymetry functions.