DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
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April 24, 2017

Luneau SAS
Isabelle Durand
Quality/ RA Manager
1 Ave de Malaguet
Prunay-Le-Gillon, FR 28360

Re: K162067
Trade/Device Name: VX130 Ophthalmic Diagnostic Device
Regulation Number: 21 CFR 886.1930
Regulation Name: Tonometer and Accessories
Regulatory Class: Class II
Product Code: HKX
Dated: March 15, 2017
Received: March 17, 2017

Dear Isabelle 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 Industry and Consumer Education 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" (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 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 Industry and Consumer Education 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,

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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K162067

Device Name
VX130

Indications for Use *(Describe)*

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 corneal thickness map.
Scheimpflug imaging.
Anterior chamber imaging.
Pupil image.
Image of the cornea relative to the iris.

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)

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510(k) Summary

VX130 ophthalmic diagnostic device

April 24th, 2017

I. SUBMITTER

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II. DEVICE

Name of Device: VX130 ophthalmic diagnostic device
Common name: Ophthalmic diagnostic device
Classification: tonometer , AC powered
Regulatory class: II
Product code: HKX
Regulation number: 886.1930

III. PREDICATE DEVICES

The VX130 is claimed to be substantially equivalent to the following currently marketed devices:

. **VX120 Ophthalmic Diagnostic Device**

Manufacturer: LUNEAU SAS
FDA K143086 issued June 1, 2015.
Product code: HKX

. **CM3910 ROTATING DOUBLE SCHEIMPFLUG CAMERA (Galilei G4)**

Manufacturer: SIS LTD. SURGICAL INSTRUMENT SYSTEMS
Allmendstrasse 11
Port Bern, SWITZERLAND CH - 2562
FDA K051940 issued July 15, 2005.
Product code: MXK

The VX130 is equivalent to VX120 for tonometry and pachymetry functions and other functions not subject to 510(k) : combined wave front aberrometer, corneal topographer and retroilluminator. It is equivalent to CM3910 for its pachymetry function.

IV. DEVICE DESCRIPTION

The VX130 is a multifunctional ophthalmic diagnostic device.

The VX130 combined wavefront aberrometer, corneal topographer, cataract screening 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. A linear scanning Scheimpflug pachymeter measures the thickness of the cornea by illuminating it with a slit of light and photographing it using the Scheimpflug technique. Anterior and posterior corneal shape are also measured from the Scheimpflug images. 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 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

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

Comparison with VX120

The VX130 has same hardware as VX120. The difference is that VX130 provides multi-slits of the Scheimpflug camera resulting of multiple results of the same indication in different place in the cornea as well as additional maps, while VX120 provides only one Scheimpflug image. That doesn't affect indications for use below:

"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."

This variant doesn't impact on performances and safety. VX130 is not different in safety or efficacy, and is substantially equivalent to VX120

Comparison with Galilei

Indications for use:

The pachymeter function of the VX130 has the same intended use as the Galilei G4 for 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

Characteristics	VX130	Galilei
References	User manual UM30200013	510(k) K051940
Measuring Principle	Linear scanning Scheimpflug principle for slit image photography	Rotational scan of Double-Scheimpflug slit images merged with Placido disk images.
Viewing Means	Display on built in LCD screen 10.1"	LCD on Measurement Unit, 17" monitor on table
Observation Illumination	Infrared LED 880nm for pupil and corneal illumination	Infrared LED 810nm

Flash Output Illumination	Blue LED light (UV free) 455nm, max 50µW	Blue LED light (UV free) 470nm max, 15mW sec
Photography Camera	CMOS camera	CCD camera
Display	Data digital	Data digital, displayed on a CPU
Image Resolution	1600 × 1000 pixels	1004 × 1004 pixels
Image Size	9 × 6mm	7.4 × 7.4 mm
Photographic Range	Linear 6mm	Eligible 0 to 180°
Photographic Series	30	1 to 60 images
Slit Length	8mm	15mm
Power Requirement	100-240 VAC, 50/60Hz	110/220 VAC 50/60Hz
Weight	25 kg	10Kg (Measurement Unit)

Rationale for Substantial Equivalence

The pachymeter function of the VX130 has the same intended use as the Galilei G4 for photographing the eye and taking images of the anterior segment of the eye to evaluate the thickness of the cornea.

The Galilei G4 and the VX130 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.

- The devices have the same intended use
- The devices utilize the same measuring principles (Slit Scan)
- The devices utilize the same photographic medium
- Similar measurement wavelengths are used

The devices use the same features like a

- Head stabilizing device
- Fixation target
- All devices are considered '"non-invasive" as defined in 21 CFR §812.3(k)

The VX130 for all functions other than pachymetry is identical to the VX120

Safety

The VX130 is a non-invasive diagnostic system, which contacts the patient only on his/her chin and forehead. The VX130 does not present or pose any new or additional risks for the prescribed intended uses. The light output is of an eye safe intensity and wavelength. The electrical safety requirements for medical devices are met. The VX130 is proven effective for its intended uses through internal performance tests.

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

1. Electrical safety and EMC testing were conducted on the VX130. 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: VX130 was evaluated according to ISO14971: 2012. All risks have been reduced to safe levels thus there is no conflict between risk and benefit.
4. Tests for ophthalmic products: VX130 was evaluated in accordance with ISO15004-1:2009 and ISO15004-2:2007 standards and was found to meet all requirements of the standards.
5. For optical hazards, VX130 was evaluated in accordance with IEC60825-1: 2008: the result is VX130 is laser class 1.

Tests for pachymetry:

1. A comparison study of anterior segment parameters done with VX130 and Galilei G4 shows that there are only small differences between the devices. Table 1 shows the differences between the two devices for a range of anterior segment parameters. Table 2 shows a repeatability measurement of the VX130. There is not a significant difference between the repeatability measurement and the comparison measurement. The two devices can therefore be considered equivalent.

			95% CL	
Parameter	**Average**	**Std dev**	**min**	**max**
K1 Anterior (D)	-0.27	0.17	-0.59	0.06
K2 Anterior (D)	-0.29	0.16	-0.62	0.03
Cyl Anterior (D)	-0.03	0.24	-0.51	0.45
K1 Posterior (D)	-0.09	0.06	-0.21	0.03
K2 Posterior (D)	-0.01	0.14	-0.29	0.28
Cyl Posterior (D)	0.08	0.12	-0.15	0.30
CCT (µm)	-0.43	7.45	-15.03	14.16

Table 1: Summary of the comparison of anterior segment parameters between the VX130 and Galilei G4 showing the average difference between the devices, the standard deviation of the difference and the 95% confidence levels.

Parameter	**Std dev 1**	**Std dev 2**
K1 Anterior (D)	0.173	0.132
K2 Anterior (D)	0.095	0.237
Cyl Anterior (D)	0.166	0.229
K1 Posterior (D)	0.031	0.075
K2 Posterior (D)	0.093	0.107
Cyl Posterior (D)	0.103	0.112
CCT (µm)	2.89	3.68

Table 2: Repeatability of VX130,

1) a single eye was measured ten times and the std dev was calculated.
2) 42 eyes were measured 3 times each the average std dev is shown.

VII. CONCLUSIONS

The VX130 has the same intended use, technological characteristics, and principles of operation as its predicate devices.
The technological differences between the VX130 and its predicates raise no new issues of safety and effectiveness.
Performance data demonstrates that the VX130 is as safe and effective as the predicate devices.