DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

January 29, 2015

HEINE Optotechnik GmbH & Co. KG
Mrs. Bettina Seim
Director, Regulatory Affairs
Kientalstr. 7
Herrsching, Germany 82211

Re: K142837
Trade/Device Name: HEINE SIGMA® 250 and 250 M2
Regulation Number: 21 CFR 886.1570
Regulation Name: Ophthalmoscope
Regulatory Class: Class II
Product Code: HLJ
Dated: December 17, 2014
Received: December 23, 2014

Dear Mrs. Seim:

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" (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 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,

Kesia Y. Alexander -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

Indications for Use

510(k) number (if known):
Device Name: HEINE SIGMA ® 250
HEINE SIGMA ® 250 M2

Indications For Use:
The HEINE SIGMA® 250 (M2) are battery powered indirect ophthalmoscopes for medical professionals, containing illumination and viewing optics intended to examine the media (cornea, aqueous, lens, vitreous) and the retina of the eye.

Prescription Use___X____ AND/OR Over-The-Counter Use_____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

HEINE

510(k) Summary of Safety and Effectiveness

In accordance with the requirements of the Safe Medical Device Act, HEINE Optotechnik GmbH & Co. KG herewith submits a Summary of Safety and Effectiveness.

Submitter Information:

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Date Prepared: September 22, 2014

Device(s) Identification:

Device Trade Name: HEINE SIGMA® 250 (M2)

Common Name: (indirect) Ophthalmoscope

Classification of the device:

Device Classification Name: Ophthalmoscope
Product Code: HLJ
Device Classification No.: Part 886.1570

HEINE

Panel: Ophthalmic Devices (86)
Regulatory Status: Class II

Device Description:

The HEINE SIGMA® 250 (M2) are indirect ophthalmoscopes, worn on the user's head to provide illumination and viewing optics in order to examine the media and the retina of a patient`s eye. The indirect ophthalmoscopes are battery operated.

Intended Use:

The HEINE SIGMA® 250 (M2) are battery powered indirect ophthalmoscopes for medical professionals, containing illumination and viewing optics intended to examine the media (cornea, aqueous, lens, vitreous) and the retina of the eye.

Predicate Device:

Device Trade Name: HEINE OMEGA® 500
Applicant: HEINE Optotechnik GmbH & Co. KG
510(k) No.: K123316

The indirect ophthalmoscopes HEINE SIGMA® 250 (M2) are considered substantial equivalent to the HEINE OMEGA® 500 Ophthalmoscope (K123316).

There is no significant difference in intended use or technology.

	SIGMA 250	SIGMA 250 M2	HEINE OMEGA® 500	Assessment
Intended Use	The HEINE SIGMA® 250 (M2) is a battery powered indirect ophthalmoscope for medical professionals, containing illumination and viewing optics intended to examine the media (cornea, aqueous, lens, vitreous) and the retina of the eye.	The HEINE SIGMA® 250 (M2) is a battery powered indirect ophthalmoscope for medical professionals, containing illumination and viewing optics intended to examine the media (cornea, aqueous, lens, vitreous) and the retina of the eye.	The indirect ophthalmoscope HEINE OMEGA® 500 is an AC-powered or battery powered device for medical professionals, containing illumination and viewing optics intended to examine the media (cornea, aqueous, lens, vitreous) and the retina of the eye.	Equivalent
Type	Binocular (Headband and Spectacles mounted)	Binocular (Headband and Spectacles mounted)	Binocular (Headband mounted)	Similar

	SIGMA 250	SIGMA 250 M2	HEINE OMEGA® 500	Assessment
Method of operation	Used to examine the retina by an examiner in a specified distance to the eye	Used to examine the retina by an examiner in a specified distance to the eye	Used to examine the retina by an examiner in a specified distance to the eye	Equivalent
Illumination	White LED, 3V	White LED, 3V	White LED, 6V / 6V, 5 Watt Xenon Halogen bulb	Equivalent
Selectable filter	Red-free	Red-free	Blue, yellow, red-free, diffuser	Similar
Safety filter IR blocker	LED light source, no IR radiation	LED light source, no IR radiation	Permanent	Similar
Light Output[1]	444lx (@ 210mA) 615lx (@ 350mA)	444lx (@ 210mA) 615lx (@ 350mA)	507 lx (max.) / 258 lx (max.)	Similar
Light apertures[1]	Small circle: n/a	Small circle: 22,5mm	Small circle: 18 mm	Similar
	Middle circle: 35mm	Middle circle: n/a	Middle circle: 39 mm	Similar
	Large circle: 80mm	Large circle: 83 mm	Large circle: 74 mm	Similar
Inter pupillary distance adjustment	47mm – 72mm	47mm – 72mm	46 – 74 mm	Similar
Data collection and/or display system	None	None	None	Equivalent
Lens power viewing optics	+2 diopter	+2 diopter	+2 diopter	Equivalent
Power sources	n/a	n/a	Wireless battery pack	Not existing
	n/a	n/a	Wall mounted unit	Not existing
	Belt battery pack	Belt battery pack	Belt battery pack	Equivalent
Brightness controls	Control dial	Control dial	Control dial	Equivalent
Maximum temperature of parts of the device held by the operator or accessible to the patient	Complies with IEC 60601-1	Complies with IEC 60601-1	Complies with IEC 60601-1	Equivalent

	SIGMA 250	SIGMA 250 M2	HEINE OMEGA® 500	Assessment
Flammability of materials	Low probability. All measures have been taken to use self-extinguishing materials which are either of flame classification HB or V-O (UL94). The system is illuminated using a LED and all materials used in the vicinity are specially designed to safely operate in high temperature environments.	Low probability. All measures have been taken to use self-extinguishing materials which are either of flame classification HB or V-O (UL94). The system is illuminated using a LED and all materials used in the vicinity are specially designed to safely operate in high temperature environments.	Low probability. All measures have been taken to use self-extinguishing materials which are either of flame classification HB or V-0 (UL94). The system is illuminated using a LED or 5W XHL Xenon Halogen lamp and all materials used in the vicinity are specially designed to safely operate in high temperature environments.	Equivalent

	Note 1: The measurements are taken from 500 mm in front of the instrument.

Summary of Non-Clinical Performance Testing:
The HEINE SIGMA® 250 (M2) indirect ophthalmoscopes were tested according to the “Ophthalmoscope Guidance” in respect to optical radiation hazard with ophthalmoscopes (ISO 10943). Additionally testing in accordance with applicable requirements of ISO 15004-2 “Ophthalmic instruments – Fundamental requirements and test methods” has been performed.

Conclusion:
HEINE Optotechnik believes that the HEINE SIGMA® 250 (M2) indirect ophthalmoscopes are substantially equivalent to the currently legally marketed devices. They do not introduce new indications for use, have the same technological characteristics, and do not introduce new potential hazards or safety risks.