DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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May 18, 2015

HEINE Optotechnik GmbH & Co. KG
c/o Ms. Belinda Labourdette
Regulatory Affairs Liaison/Executive Assistant
HEINE USA, Ltd.
10 Innovation Way
Dover, NH 03830

Re: K142486
Trade/Device Name: HEINE BETA 200®, HEINE BETA 200 S®, and HEINE K 180® Direct Ophthalmoscopes
Regulation Number: 21 CFR 886.1570
Regulation Name: Ophthalmoscope
Regulatory Class: Class II
Product Code: HLJ
Dated: March 26, 2015
Received: April 10, 2015

Dear Ms. Labourdette:

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 -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)*
K142486

Device Name
HEINE BETA® 200 Ophthalmoscope
HEINE BETA® 200S Ophthalmoscope
HEINE K180® Ophthalmoscope

Indications for Use *(Describe)*
HEINE Direct ophthalmoscopes are intended for examination of the media (cornea, aqueous humour, lens, vitreous humour) and retina of the eye.

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.

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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:

HEINE Optotechnik GmbH & Co. KG
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82211 Herrsching
Germany
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Owner/Operator Number: 9003020

Official Contact Person:

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Date Prepared: July 3rd, 2014

Device(s) Identification:

Device Trade Name:
HEINE BETA® 200 Ophthalmoscope
HEINE BETA® 200S Ophthalmoscope
HEINE K180® Ophthalmoscope

Common Name: (direct) Ophthalmoscope

Classification of the device:

Device Classification Name:	Ophthalmoscope
Product Code:	HLJ
Device Classification No.:	Part 886.1570
Panel:	Ophthalmic Devices (86)
Regulatory Status:	Class II

HEINE

Device Description:
HEINE BETA® 200, HEINE BETA® 200S and HEINE K180® Ophthalmoscopes are battery powered hand-held devices to that provide illumination, viewing optics, apertures and filters in order to examine the media and the retina of a patient's eye. Each device consists of an instrument head with bulb and a battery handle that can be attached to the instrument head. The devices are differentiated by the various number and type of apertures and filters and by the different range and number of corrective lenses.

Intended Use:

HEINE Direct ophthalmoscopes are intended for examination of the media (cornea, aqueous humour, lens, vitreous humour) and retina of the eye.

Predicate Device:

Device Trade Name:	HEINE mini 3000® LED Ophthalmoscope
Applicant:	HEINE Optotechnik GmbH & Co. KG
510(k) No.:	K123587 (March 22, 2013)

The HEINE BETA® 200, BETA 200S and K180 Ophthalmoscopes are considered substantially equivalent to the HEINE mini 3000® LED Ophthalmoscope (K123587). There is no significant difference in intended use or technology.

Summary of Non-Clinical Performance Testing:
The HEINE BETA 200®, BETA 200 S and K 180 Ophthalmoscopes are tested according to the "Ophthalmoscope Guidance" in respect to optical radiation hazard with ophthalmoscopes (ISO 10942). Additional 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 BETA 200®, BETA 200 S and K 180 Ophthalmoscopes are substantially equivalent to the currently legally marketed device HEINE mini3000® LED Ophthalmoscope (K123587). They do not introduce new indications for use, they have the same technological characteristics and they do not introduce new potential hazards or safety risks.