**HEINE**

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K123587

MAR 22 2013

# 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 3rd, 2012

**Device(s) Identification:**

Device Trade Name: HEINE mini3000® LED Ophthalmoscope
Common Name: 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

**Device Description:**
The HEINE mini 3000® LED Ophthalmoscope is a battery powered hand-held device to provide illumination and viewing optics in order to examine the media and the retina of a patient's eye. It consists of an instrument head and a battery handle that can be screwed onto the instrument head. The ophthalmoscope can be either operated by replaceable AA batteries or a rechargeable option in combination with the HEINE mini NT® charger.

**Intended Use:**
The HEINE mini 3000® LED Ophthalmoscope is a battery powered hand-held device 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: | Piccolight® E50 |
| Applicant: | Kirchner & Wilhelm GmbH & CO. KG |
| 510(k) No.: | K070270 |

The HEINE mini3000® LED Ophthalmoscope is considered substantial equivalent to the Piccolight® E50 Ophthalmoscope (K070270).
There is no significant difference in intended use or technology.

| | HEINE mini3000® LED Ophthalmoscope | Piccolight® E50 | Assessment |
|---|---|---|---|
| **Intended Use** | The HEINE mini3000® LED Ophthalmoscope is a battery powered hand-held device for medical professionals, containing illumination and viewing optics intended to examine the media (cornea, aqueous, lens, vitreous) and the retina of the eye. | The Piccolight® E50 ophthalmoscope is intended to be used to examine the cornea, aqueous, lens, vitreous and retina of the eye. | same |
| **Type** | Monocular | Monocular | same |
| **Method of operation** | Used to examine the retina by an examiner in a specific distance to the eye. | Used to examine the retina by an examiner in a specific distance to the eye. | same |
| **Illumination type** | LED | Halogen filament bulb | refer to justification 1 |
| **Exposure parameters** | Emission of a white LED | Emission of 2.5 V halogen bulb | refer to justification 1 |
| **Light output**[1] | 542 lux | 46 lux | refer to justification 1 |
| **Filter** | Red free filter | none | refer to justification 2 |
| **Service life of illuminant** | 50.000 hours | approx. 15 hours | refer to justification 3 |
| **Diopters** | + 20D to –20D | + 20D to –20D | same |
| **Lens power viewing optics** | Diopter of used lens in steps:<br>-20, -15, -10, -8, -6, -4,-3, -2, -1,<br>0, 1, 2, 3, 4, 6, 8, 10, 15, 20 | Diopter of used lens in steps:<br>-20, -15, -10, -8, -6, -4,-3, -2, -1,<br>0, 1, 2, 3, 4, 6, 8, 10, 15, 20 | same |
| **Light apertures**[1] | small circle D = 13,8 mm<br>large circle D = 27,3 mm<br>semicircle<br>medium circle with reticle D = 3,1 mm | Large circle D = 24,00 mm | refer to justification 4 |
| **Supply voltage** | 2.5 V | 2.5 V | same |
| **Power sources**[2] | 2 alkaline cells (size LR6/AA) /<br>HEINE mini 2Z rechargeable battery | Battery | refer to justification 5 |

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|---|---|---|---|
| **Brightness controls** | none | none | same |
| **Maximum temperature of parts of the device held by the operator or accessible to the patient** | Complies with IEC 60601-1 for temperatures of external surfaces and controls[3] | Complies with IEC 60601-1 for temperatures of external surfaces and controls | same |
| **Flammability of materials** | Low probability. All measures have been taken to use self-extinguishing materials. The system is illuminated using a 3W LED lamp and all materials used in the vicinity are specially designed to safely operate in high temperature environments. | Fiber-glass reinforced plastic Polyamide 6 GF30C | same |
| **Cleaning and Disinfection** | **Cleaning**<br>Cleaning or disinfection by spraying or immersion as well as sterilization is not allowed and will damage the instrument!<br><br>*Instrument head*<br>The housing can be wiped clean with a damped cloth. Glass surfaces can be cleaned with a cotton wool.<br><br>*Battery handle*<br>The handle can be cleaned with a damp cloth (e.g. alkaline or pH- neutral detergent).<br><br>**Disinfection**<br>The instrument head and handle can be disinfected with CIDEX® OPA by wiping it with a soft cloth moistened with disinfectant for 5 minutes. | **Cleaning**<br>In order to avoid dirt accumulation and dust always store the unit in the packaging. The outside of the unit can be cleaned with a damp, soft and fluff-free fabric. For disinfection, a fabric moistened with alcohol can be used. If necessary, the pane of the observation window can be cleaned with a cotton plug and some alcohol. Please do not press the pane! Never bring the ophthalmoscope into contact with liquid and make sure that no liquid penetrates the housing!<br>Since the ophthalmoscope is not desired for operations, simple cleaning and/or disinfection with a surface disinfectant on an alcoholic base is sufficient. Do not use any scrubbing cleaning agents! The unit cannot be sterilized. | same |

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| Note 1: Measurements taken 200 mm from output (direct ophthalmoscopes), large circle aperture |
| Note 2: All power sources comply with the relevant standard of IEC 60601-1 and IEC 60601-1-2. |
| Note 3: Chapter 11 of this submission contains the corresponding test report No. E256178-A18-CB-1. Please refer to clause 42 of test report E256178-A18-CB-1 for further details. |
| Justification 1<br>The HEINE mini3000® LED Ophthalmoscope complies with requirements for group 2 instrument of ISO 15004-2:2007. |
| Justification 2<br>The Red free filter is used to enhance the contrast of the fundus image. Diagnosis is even possible without it, but may take longer. Thus the Red-free filter does not influence the safety and effectiveness compared to the predicate device. |
| Justification 3<br>The minimum lifetime of the used LED in the HEINE mini3000® LED Ophthalmoscope is 50.000 hours. Assuming the use of the LED for a continuous period of 10 hours at 220 working days a year, this would calculate to 22 years of use. Thus does not influence the effectiveness and safety compared to the predicate device. |
| Justification 4<br>Offering several apertures with different diameters gives the examiner more flexibility to adjust the instrument to the examined eye. Thus does not influence the effectiveness and safety compared to the predicate device. |
| Justification 5<br>The predicate device uses the same battery type as the HEINE mini3000® LED Ophthalmoscope. In addition, a rechargeable battery is available for the HEINE mini3000® LED Ophthalmoscope. Thus does not influence the effectiveness and safety compared to the predicate device. |

**Summary of Non-Clinical Performance Testing:**
The HEINE mini 3000® LED Ophthalmoscope is tested according to the "Ophthalmoscope Guidance" in respect to optical radiation hazard with ophthalmoscopes (ISO 10942). 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 mini 3000® LED Ophthalmoscope is substantially equivalent to the currently legally marketed devices. It does not introduce new indications for use, have the same technological characteristics and do not introduce new potential hazards or safety risks.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

March 22, 2013

HEINE Optotechnik GmbH & Co. KG
% Mr. Alexander Schapovalov
TUV America, Inc.
1775 Old Highway 8 NW, Suite 104
New Brighton, MN 55112

Re: K123587
Trade Name: HEINE mini3000® LED Ophthalmoscope
Regulation Number: 21 CFR 886.1570
Regulation Name: Ophthalmoscope
Regulatory Class: Class II
Product Code: HLJ
Dated: March 5, 2013
Received: March 7, 2013

Dear Mr. Schapovalov:

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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,

Deborah L. Falls -S FDA

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: K123587

Device Name: HEINE mini 3000® Ophthalmoscope

Indications For Use:

The HEINE mini 3000® LED Ophthalmoscope is a battery powered hand-held device 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)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Dexiu Shi

Digitally signed by Dexiu Shi -S
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, cn=Dexiu Shi -S, 0.9.2342.19200300.100.1.1=13000157347
Date: 2013.03.15 16:45:33 -04'00'

(Division Sign-Off)
Division of Ophthalmic and Ear, Nose and Throat Devices

510(k) Number K123587