K123316

HEINE

HEINE Optotechnik GmbH & Co. KG · Kientalstr. 7 · 82211 Herrsching · Germany
Tel. +49(0)8152/38-0 · Fax +49(0)8152/38-202 · E-Mail: info@heine.com · **www.heine.com**

FEB 2 6 2013

510(k) Summary of Safety and Effectiveness

Submitter Information:

HEINE Optotechnik GmbH & Co. KG
Kientalstr. 7
82211 Herrsching
Germany
Registration Number: 1000379039
Owner/Operator Number: 9003020

Official Correspondent:

Mr. Jörg Rönnau
Director Regulatory Affairs
HEINE Optotechnik GmbH & Co. KG
Phone: +49 8152 38 0

US Agent (Contact):

Benoit St. Jean
HEINE USA, ltd.
10 Innovation Way
Dover, NH 03820 USA
Phone: +1 603 7427217
E-mail: Bstjean@heine-na.com

Date Prepared: September 3rd, 2012

Device(s) Identification:

Device Trade Name: HEINE OMEGA® 500
Common Name: Indirect ophthalmoscope

Classification of the device:

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

Device Description:
The HEINE OMEGA® 500 is an indirect ophthalmoscope, 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 ophthalmoscope can be operated either by rechargeable battery or directly by mains power supply.
The HEINE OMEGA® 500 allows wireless comfortable movement for the user and mobile charging (depending on chosen power source).

Intended Use:
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.

Predicate devices:

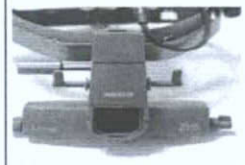
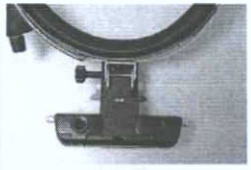
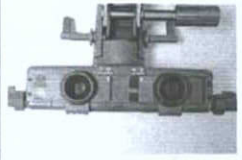
Device Trade Name:	Vantage Plus Binocular Indirect Ophthalmoscope
Applicant:	Keeler Instruments Inc.
510(k) No.:	K060822
Device Trade Name:	NEITZ Binocular Indirect Ophthalmoscope IO-A
Applicant:	NEITZ Instruments Company, Ltd.
510(k) No.:	K942712
Device Trade Name:	Model #12000 Binocular Indirect Ophthalmoscope
Applicant:	Welch Allyn, Inc.
510(k) No.:	K930023

The HEINE OMEGA 500 is considered substantial equivalent to the Vantage Plus Binocular Indirect Ophthalmoscope (K060822), NEITZ Binocular Indirect Ophthalmoscope IO-A (K942712) and Welch Allyn Model #12000 Binocular Indirect Ophthalmoscope (K930023).

	HEINE OMEGA 500	Keeler Vantage Plus	NEITZ IO-a LED	Welch Allyn Model #12000	Assessment
510(k) applied (predicate devices)	New device, for which a 510(k) is applied	510(k) Number: K060822	510(k) Number: K942713	510(k) Number: K930023	same
Indication for use	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 Source: Instructions for use	The Keeler Vantage Plus Indirect Ophthalmoscope is intended to be used to examine the Cornea, aqueous, lens vitreous and retina of the eye. Source: 510(k) K060822	An ophthalmoscope is an AC-powered or battery-powered device containing illumination and viewing optics intended to examine the media (cornea, aqueous, lens, and vitreous) and the retina of the eye. Source: 510(k) K942713, Regulation Number: 886.1570	An ophthalmoscope is an AC-powered or battery-powered device containing illumination and viewing optics intended to examine the media (cornea, aqueous, lens, and vitreous) and the retina of the eye. Source: 510(k) K930023, Regulation Number: 886.1570	same
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	Used to examine the retina by an examiner in a specified distance to the eye	same
Technology	The HEINE OMEGA 500 indirect ophthalmoscope has two main elements: 1. The illumination element 2. The viewing element	The Keeler Vantage Plus, indirect ophthalmoscope has two main elements: 1. The illumination element 2. The viewing element	The Neitz IO-a LED indirect ophthalmoscope has two main elements: 1. The illumination element 2. The viewing element	The Welch Allyn Model #12000 indirect ophthalmoscope has two main elements: 1. The illumination element 2. The viewing element	same
Type / Design	indirect ophthalmoscope Binocular (Headband mounted)	indirect ophthalmoscope Binocular (Headband mounted)	indirect ophthalmoscope Binocular (Headband mounted)	indirect ophthalmoscope Binocular (Headband mounted)	same
Exposure Parameter Safety Infrared Filter (IR-Blocker)	Permanent	Permanent	Not available	Not available	same

	HEINE OMEGA 500		Keeler Vantage Plus		NEITZ IO-a LED	Welch Allyn Model #12000	Assessment
Selectable filter	Blue, yellow, red-free, diffuser		Blue, red-free, diffuser		Cobalt blue, red-free	Cobalt blue, yellow, red-free, diffusor	same
Exposure Parameter Energy Delivered (Light Output) Measured in a distance of 500 mm	507 lx (max.)	258 lx (max.)	901 lx (max.)	913 lx (max.)	600 lx (max.)	Information not available	refer to justification 1)
min. Irradiance (for retinal imaging)	LED 8,81 mW/cm²	Halogen 11,42 mW/cm²	LED 54,87 mW/cm²	Halogen 26,53 mW/cm²	LED 22,10 mW/cm²	Information not available	refer to justification 1)
max. Irradiance (for retinal imaging)	LED 323,54 mW/cm²	Halogen 465,77 mW/cm²	LED 597,66 mW/cm²	Halogen 423;29 mW/cm²	LED 515,03 mW/cm²	Information not available	refer to justification 1)
Power sources (Energy used)	Wireless battery pack mPack unplugged: Nominal voltage: 7.4V 1850mAh		Wireless battery pack (Standard Lithium battery): Nominal voltage: 7.4V 1800mAh		Wireless battery pack (same as 2400RD): nominal voltage: 2.4 V min. 1900mAh	Not Available	same
	Wall mounted unit (EN50 mPack/EN50) Mains voltage: 100-240Vac		Wall pack Input mains data: 100-240Vac		Not available	Wall/Desk Power Source: Input: 96-130Vac	
	Belt battery pack (mPack): Nominal voltage: 7.2V 4200mAH		Belt battery pack (Smart pack): Nominal voltage: 7.2V 2500 mAh		Belt battery pack (2400RD) Nominal voltage: 2.4V min. 1900mAH	Belt battery pack (Portable Power Source): nominal voltage: 4.8V 1800mAh	
Biocompatibility	No contact to the patient		No contact to the patient		No contact to the patient	No contact to the patient	same
Material	Aluminum Leather Brass Steel Plastics		Aluminum Leather Brass Steel Plastics		Aluminum Leather Brass Steel Plastics	Aluminum Brass Steel Plastics	same
Standard for electrical safety	Complies with IEC 60601-1		Complies with BS EN ISO 60601-1		Information not available	Complies with IEC 601-1	same

	HEINE OMEGA 500	Keeler Vantage Plus	NEITZ IO-a LED	Welch Allyn Model #12000	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-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.	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 and all materials used in the vicinity are specially designed to safely operate in high temperature environments.	not available	not available	same
Performance based on Ophthalmo-scope Guidance for industry and ISO 10943	Fulfilled, refer to 510(k) chapter 18c	Fulfilled	Fulfilled	Fulfilled	same
Illumination	White LED, 6V / 6V, 5 Watt Xenon Halogen bulb	White LED, 6V / 6V, 5 Watt Xenon filament bulb	White LED	4,65V, 12 Watt Halogen bulb	same
Light apertures[Note1]	Small circle: 18 mm	23 mm	19 mm	20 mm	refer to justification 2)
	Middle circle: 39 mm	51 mm	50 mm	50 mm	
	Large circle: 74 mm	68 mm	80 mm	80 mm	
Inter pupillary distance adjustment	46 – 74 mm	48 – 76 mm	54 – 74 mm	49 – 74 mm	refer to justification 3)
Data collection and/or display system	None	None	None	None	same
Lens power viewing optics	+2 diopter	+2 diopter	not available	+2 diopter	same
Brightness controls	Control dial	Control dial	Control dial	Control dial	same

	HEINE OMEGA 500	Keeler Vantage Plus	NEITZ IO-a LED	Welch Allyn Model #12000	Assessment
Maximum temperature of parts of the device held by the operator or accessible to the patient	Complies with IEC 60601-1	Complies with BS EN ISO 60601-1	Information not available	Complies with IEC 601-1	same
Product views[Note2] **Total view**					same
operator's view					
left side					
Backside of the headband					

	HEINE OMEGA 500	Keeler Vantage Plus	NEITZ IO-a LED	Welch Allyn Model #12000	Assessment
Cleaning	Before cleaning, disconnect from the power source. The instrument and the loupe may be wiped clean with a non-shedding damp or dry cloth. Wipe the headband with a clean, absorbent, non-shedding cloth dampened with a water/detergent solution (2% by volume). Ensure that excess solution does not enter the instrument. Use caution to ensure cloth is not saturated with solution. The XHL / LED lamp can be cleaned, with a dry cloth if necessary.	Only manual non-immersion cleaning as described below should be used for the instrument. Do not autoclave or immerse in cleaning fluids. Always disconnect power supply from source before cleaning. Wipe external surface with a clean absorbent, non-shedding cloth dampened with a water/detergent solution (2% by volume) or water/isopropyl alcohol solution (70% by volume). Ensure that excess solution does not enter the instrument. Use caution to ensure cloth is not saturated with solution. Surfaces should be carefully hand dried using a clean non shedding cloth. Safely dispose of used cleaning materials.	The newly adopted Head Pad of Wet Suit Material secures the durable wearing of the head band and the utmost comfort. This Washable material is ideal for keeping your instrument neat and clean in use.	The glass cover on the front of the BIO, the glass lenses in the oculars and the teaching mirror can be cleaned with a soft cloth moistened with alcohol. The leather cushions on the headband may be removed and wiped with soapy water. The remainder of the BIO may be wiped with a soft cloth that has been moistened in alcohol. Avoid using harsh cleaning fluids or cloth which are excessively moist on any part of this instrument.	same
Disinfection	The instrument headband can be disinfected with CIDEX® OPA by wiping it with a soft cloth moistened with disinfectant for 5 minutes. The use of a spray disinfectant and soaking or disinfection in a machine is not permitted. Sterilisation of OMEGA® 500 is not allowed	Do not autoclave or immerse in cleaning fluids. No further information denoted	no information denoted	no information denoted	same

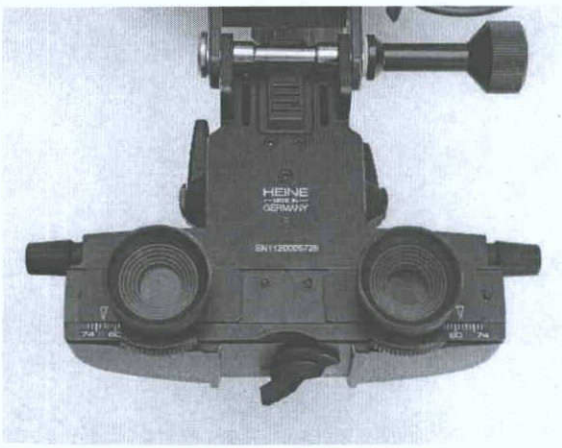
	Note 1: The measurements are taken from 500 mm in front of the instrument.
	Note 2: Assessment concerning safety statements
	Justification 1: The light output values stated in the table above are the maximum possible values of the devices. The light output value of each device is adjustable from a minimum level up to 100% by an integrated control dial. The FDA Guidance of Industry "Ophthalmoscope Guidance" advises the manufacturer to provide the following information to the user: "[...] the brightness setting should not exceed what is needed to provide clear visualization of the target structures. [...]". This reflects the market experience of HEINE that doctors accept or even prefer using low levels of illumination. Moreover, these low levels provide the advantage of longer exposure durations until the limits of radiation hazards are reached. Therefore, the probability of ocular damage is less in comparison to exposures with higher illumination. The high light output of the Keeler device was also discussed critically in [12a]. The "minimum retinal irradiance required for viewing human fundi in indirect ophthalmoscopy" is discussed in [12b]. The authors concluded "... that the minimum retinal irradiance needed for viewing human fundi is less than ... 6,3mW/cm²)". To determine the maximum retinal irradiance of the HEINE OMEGA 500 we set the brightness control of our device to the maximum level in the same way as we did for the determination of exposure parameter in the comparison table above. Then we determined the irradiance according to the test method published in [12c] The measured retinal irradiance of HEINE OMEGA 500 ophthalmoscopes is 323,54 mW/cm² (approximately 51 times higher than the required minimum level) for the device equipped with LED illumination and 465,77 mW/cm² (approximately 74 times higher than the required minimum level) for the device equipped with XHL Xenon Halogen Bulb. [12d] The irradiance of 323,54 mW/cm² of the HEINE OMEGA 500 with LED is lower than the irradiance of the predicate devices. However as indicated [12b] a minimum retinal irradiance of 6,3 mW/cm² is needed for viewing the human fundi. Taking into account these facts we believe, that the light output level of the HEINE OMEGA 500 does not affect the safety or the effectiveness of the device compared to the predicate devices. We regard our device as equivalent. The different ratios between the measured exposure parameters for the energy delivered (Light Output) measured in lux and the Min and Max. Irradiance measured in mW/cm² can be explained by the following facts: 1. The lux (symbol: lx) is the SI unit of illuminance and luminous emittance, measuring luminous flux per unit area. It is equal to one lumen per square meter. In photometry, this is used as a measure of the intensity, as perceived by the human eye, of light that hits or passes through a surface. It is analogous to the radiometric unit watts per square meter, but with the power at each wavelength weighted according to the luminosity function, a standardized model of human visual brightness perception. In English, "lux" is used in both singular and plural. 2. The Irradiance is a physical parameter measured in "mW/cm²" solely based on physical parameters without human visual brightness perception. Therefore there is no direct correlation between the values measured in lux and the values measured in "mW/cm²" because the lux values depend heavily on the wavelength of the light whereby the Irradiance measures the power of the light in "mW/cm²" without human visual brightness perception. Both values are measured values and therefore calculations can't be provided. References: [12a] Kossol J, Cole C, Dayhaw-Barker P.: "Spectral irradiances of and maximal permissible exposures to two indirect ophthalmoscopes" in Am J Optom Physiol Opt. 1983 Jul;60(7):616-21 [12b] Rockefeller S. L. Young, Morton F. Goldberg, Gerald A. Fishman: "Letter to the editor" in Investigative Ophthalmology & Visual Science, Volume 20, Number 4, May 1981 [12c] Joseph L. Calkins and Bernard F. Hochmeier: "Retinal light exposure from ophthalmoscopes, slit lamps, and overhead surgical lamps" in Investigative

	Ophthalmology & Visual Science, Volume 19, Number 9, September 1980 [12d] Test report – Estimation of irradiance in the retinal plane of HEINE OMEGA 500 indirect ophthalmoscope", Version 1.0, 2012-10-18; HEINE Optotechnik
	Justification 2: Different patients have different anatomical pupil sizes. Therefore the possibility of adjustment of the light apertures of binocular indirect ophthalmoscopes enables the user of the device to adjust the diameter of the illuminated spot individually to the patient's eye. The HEINE OMEGA® 500 offers a slightly smaller diameter of the "small circle" than the NEITZ IO-a. The differences between the new device and the predicate devices do not affect the safety or effectiveness of the device and we regard our device as equivalent to the predicate devices
	Justification 3: The interpupillary distance adjustment of binocular indirect ophthalmoscopes allows the individual user of the device to match the distance of the oculars to the interpupillary distance of his eyes to get a singular focused image. The HEINE OMEGA® 500 provides the possibility to adjust the smallest inter pupillary distance of 46 mm. This enables users with eyes that are close together to get an optimal view through the instrument. This does not affect the safety or effectiveness of the device and we regard our device as equivalent to the predicate devices.

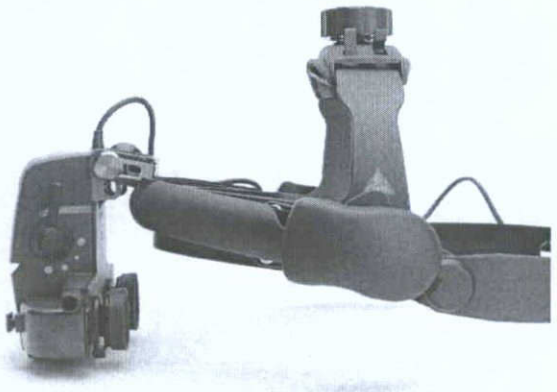
Labeling on the products:

HEINE OMEGA 500

total view from behind



operator's view

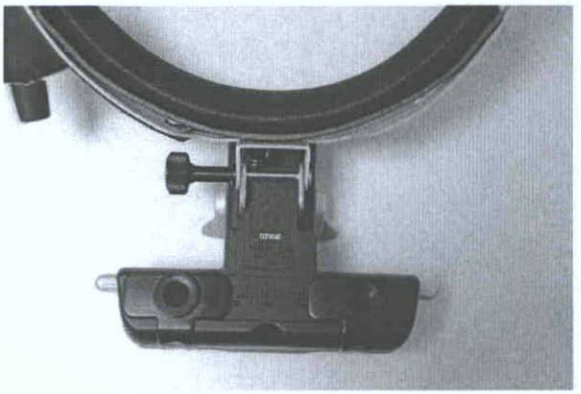


view from the left

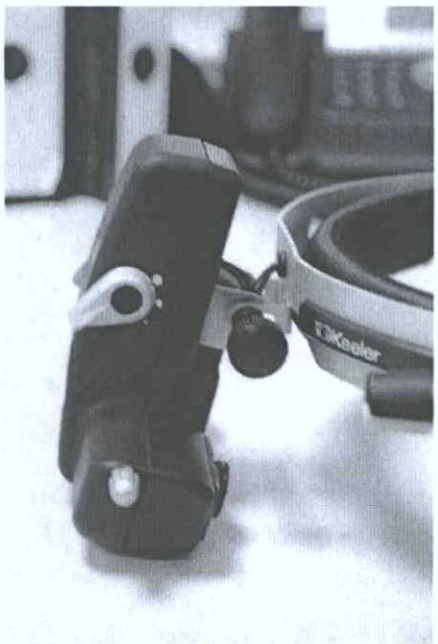
backside of the headband

Keeler Vantage Plus

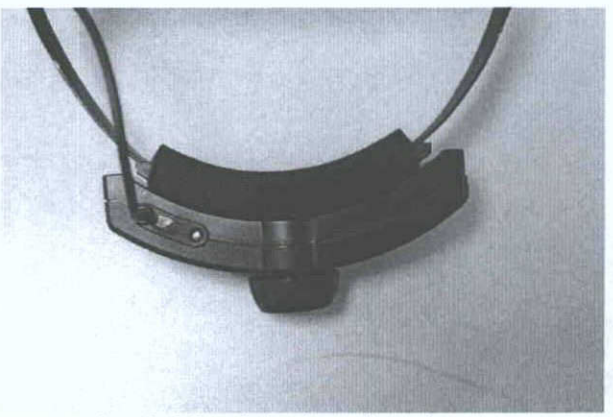
total view



operator's view



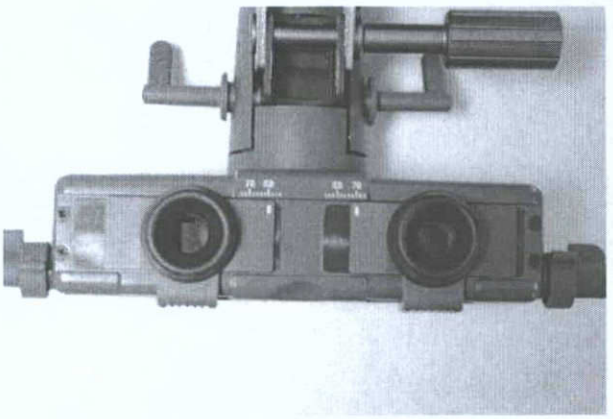
view from the left



backside of the headband

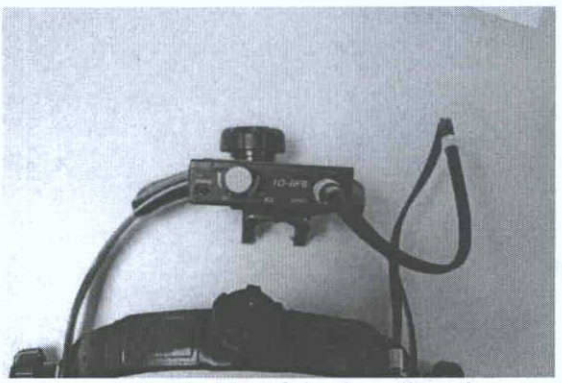
NEITZ IO-a LED

total view



operator's view

view from the left



backside of the headband

Summary of Non-Clinical Performance Testing:
The HEINE OMEGA® 500 indirect ophthalmoscope is 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 OMEGA® 500 is 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.

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

February 26, 2013

Heine Optotechnik GmbH & Co. Kg.
% Mr. Alexander Schapovalov
TUV Sud America, Inc.
1775 Old Highway 8 NW
New Brighton, MN 55112-1891

Re: K123316
Trade/Device Name: Heine Omega 500
Regulation Number: 21 CFR 886.1570
Regulation Name: Ophthalmoscope
Regulatory Class: Class II
Product Code: HLI, HLJ
Dated: February 1, 2013
Received: February 11, 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,

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 OMEGA® 500
Indications For Use:

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.

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)

Kesia Y. Alexander-S
2013.02.26 14:18:03 -05'00'

(Division Sign-Off)
Division of Ophthalmic and Ear, Nose, and Throat Devices
510(k) Number: K123316