Exhibit #4

K070270

NOV - 5 2007

KIRCHNER & WILHELM
GmbH + Co.
Medizintechnik, Germany

510(k) Summary

Name and address of sponsor of the 510(k) submission:	Kirchner & Wilhelm GmbH & Co. KG Eberhardstrasse 56 71679 Asperg Germany
Official contact person for all correspondence:	Matthias Dubb Phone: 49 7141 68188-70 Fax: 49 7141 68188-74 E-mail: Matthias.dubb@Kirchner & Wilhelm med.de
Date Prepared:	January 26, 2007
Device Name:	Piccolight® E50, Piccolight® E56, Eurolight® E10, Eurolight® E30, Eurolight® E36
Generic name of the device:	Ophthalmoscope, battery-powered
Classification, Product Code and CFR Regulation Number:	Class II HLJ 21 CFR 886.1570
Classification Panel:	Ophthalmic
Predicate Device Names and 510(k) numbers:	Uni II (K925756) RI-MINI (K932503) Ophthalmoscope (K932503) Heine Beta 200S (Device Listed by Heine USA, Ltd., establishment registration number: 1054443)

Device Description:

All Kirchner & Wilhelm ophthalmoscopes are battery powered. The Piccolight E50 and Eurolight E10 and E30 are single aperture ophthalmoscopes while the Piccolight E56 and Eurolight E36 have six apertures each. The Piccolight and Eurolight series are different in the handles, with Piccolight handles made of PA 6 GF 30% while Eurolight handles are made of metal. The Piccolight E50 and Eurolight E10 heads are same as the Eurolight E30 head except for the locking system. Similarly, but for the locking system, the Piccolight E56 and Eurolight E36 heads are the same.

Comparison with Predicate Device:

	Piccolight® E50	**Riester ophthalmoscopes Pen Scope® (K925757)**
Intended use	An ophthalmoscope is intended to be used to examine the cornea, aqueous, lens, vitreous and retina of the eye.	Same
Method of operation	Used to examine the retina by an examiner in a specific distance to the eye.	Same
Exposure parameters	Emission of 2.5 V vacuum bulb	Emission of 2.7 V vacuum bulb
data collection and/or display systems	Dioptre of used lens in steps: -20, -15, -10, -8, -6, -4,-3, -2, -1, 0, 1, 2, 3, 4, 6, 8, 10, 15, 20	Same
Flammability of materials	Fibre-glass reinforced plastic Polyamide 6 GF30C	Same
maximum temperature of parts of the device held by the operator or accessible to the patient	Ambient temperature Metal parts around the bulb: Approx. max. 50°C	Same
brightness controls	No	No
Supply voltage	2.5 V	2.7 V
Power supply	Battery powered	Same
Aperture	One aperture (large circle)	four aperture (large circle, Small circle, semi-circle, large circle with fixing cross)

All main aspects regarding the safety and effectiveness are comparable. The main difference is the difference in the number of apertures and that is not a significant difference.

	Piccolight® E56	**Riester ophthalmoscope ri-mini® (K932503)**
Intended use	An ophthalmoscope is intended to be used to examine the cornea, aqueous, lens, vitreous and retina of the eye.	same
Method of operation	Used to examine the retina by an examiner in a specific distance to the eye.	Same

Exposure parameters	Emission of 2.5 V halogen bulb	Emission of 2.5 V halogen bulb
data collection and/or display systems	Dioptre of used lens in steps: -20, -15, -10, -8, -6, -4,-3, -2, -1, 0, 1, 2, 3, 4, 6, 8, 10, 15, 20	Same
Flammability of materials	Fibre-glass reinforced plastic Polyamide 6 GF30C	Same
maximum temperature of parts of the device held by the operator or accessible to the patient	Ambient temperature Metal parts around the bulb: Approx. max. 50°C	Same
brightness controls	No	No
Supply voltage	2.5 V	2.5 V
Power supply	Battery powered	Same
Aperture	six aperture (slit diaphragm, large circle, small circle, semi-circle, red-free (green), large circle with fixing cross)  or 	four aperture (large circle, Small circle, semi-circle, large circle with fixing cross; additional red-free (green))

All main aspects regarding the safety and effectiveness are comparable. The main difference is the difference in the number of apertures with one more aperture being there in Piccolight. The additional slit diaphragm is used to differentiate the level differences (e.g, in the case of tumors or papilloedema). This has no effect on the security of the subject device as compared to the predicate.

	EUROLIGHT® E10 EUROLIGHT® E30	**Riester ophthalmoscope UNI® II (K925756)**
Intended use	An ophthalmoscope is intended to be used to examine the cornea, aqueous, lens, vitreous and retina of the eye.	Same
Method of operation	Used to examine the retina by an examiner in a specific distance to the eye.	Same
Exposure parameters	Emission of 2.5 V vacuum bulb	Emission of 2.7 V vacuum bulb, 2.5 V halogen bulb or 3.5 xenon bulb
data collection and/or display	Dioptre of used lens in steps: -20, -15, -10, -8, -6, -4,-3, -2, -1,	Same

systems	0, 1, 2, 3, 4, 6, 8, 10, 15, 20	
Flammability of materials	Fibre-glass reinforced plastic Polyamide 6 GF30C	Metal housing
maximum temperature of parts of the device held by the operator or accessible to the patient	Ambient temperature Metal parts around the bulb: Approx. max. 50°C	Same
brightness controls	Various	Various
Supply voltage	2.5 V	2,5 V
Power supply	Battery powered	Same
Aperture	one aperture (large circle)	one aperture (large circle)

All main aspects regarding the safety and effectiveness are comparable. The UNI II can also be used with halogen and xenon light. Both are brighter than light from vacuum bulb. Therefore the optical radiation exposure for the eye during the examination is higher than by using a vacuum bulb. The different housing materials are not relevant for the safety of the instrument. The temperature which gets generated during examination is not able to inflame the used materials.

	EUROLIGHT® E36	**HEINE BETA 200 S® ophthalmoscope**
Intended use	An ophthalmoscope is intended to be used to examine the cornea, aqueous, lens, vitreous and retina of the eye.	Same
Method of operation	Used to examine the retina by an examiner in a specific distance to the eye.	Same
Exposure parameters	Emission of 2.5 V halogen bulb	Emission of 2.5 V or 3.5 V xenon halogen bulb
data collection and/or display systems	Dioptre of used lens in steps: -20, -15, -10, -8, -6, -4,-3, -2, -1, 0, 1, 2, 3, 4, 6, 8, 10, 15, 20	Dioptre of used lens in steps: + in 1D step 1-10, 15, 20, 40 - in 1D step 1-10, 15, 20, 25, 35
Flammability of materials	Fibre-glass reinforced plastic Polyamide 6 GF30C	Polycarbonate
maximum temperature of parts of the device held by the operator or accessible to the patient	Ambient temperature Metal parts around the bulb: Approx. max. 50°C	Same
brightness	Various	Various

controls		
Supply voltage	2.5 V	2.5 V or 3.5 V
Power supply	Battery powered	Same
Aperture	six aperture  or 	six aperture  or 

All main aspects regarding the safety and effectiveness are comparable. The different housing materials are not relevant for the safety of the instrument.

Intended Use:

An ophthalmoscope is intended to be used to examine the cornea, aqueous, lens, vitreous and retina of the eye.

Non-Clinical Testing:

The ophthalmoscopes conform to ISO 10942; IEC 60601-1, and IEC 60601-1-2.

Clinical Testing:

Not applicable

Conclusion:

The ophthalmoscopes referred to in this 510(k) submission are substantially equivalent to the predicates and raise no issues of safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV - 5 2007

Kirchner & Wilhelm GmbH & CO. KG
c/o Natalya Valerio
mdi Consultants Inc.
55 Northern Blvd., Suite 200
Great Neck, NY 11021

Re: K070270
Trade/Device Name: Piccolight E50 & E56 and Eurolight E10, E30 & E36
Regulation Number: 21 CFR 886.1750
Regulation Name: Ophthalmoscope
Regulatory Class: Class II
Product Code: HLJ
Dated: October 18, 2007
Received: October 26, 2007

Dear Ms. Valerio:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

M. B. Eydelman, MD

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): Not Assigned as of this time K070270

Device Name: Piccolight® E50, Piccolight® E56, Eurolight® E10, Eurolight® E30, Eurolight® E36 Ophthalmascopes

Indications for Use:

An ophthalmoscope is intended to be used to examine the cornea, aqueous, lens, vitreous and retina of the eye.

10/31/2007

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

510(k) Number K070270

Prescription Use X
(Per 21 CFR 801 Subpart D)

OR

Over-The Counter Use
(21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)