K063640

9. Certification
9.1 Summary for public disclosure

DEC 18 2006

Submitter information:

Applicant:	Kowa Company, Ltd. 4-14, Nihonbashi-honcho 3-Chome Chuo-ku, Tokyo, 103-8433 Japan Phone: +81-3-3279-7329 Fax: +81-3-3245-1109
Contact:	Satohiko Takanashi, PE
E-mail address:	s-takana@kowa.co.jp

Date summary prepared:	December 6, 2006

Device identification:

Device trade name:	KOWA SL-15
Classification name:	Biomicroscope, Slit lamp, AC-powered
Product code:	HJO

Intended use:
KOWA SL-15 is an ophthalmic device indicated for non-invasive illumination, magnification and observation of the human eye. It consists of a hand-held, battery powered slit-lamp biomicroscope with viewing and illumination optical systems and an AC-powered stand.

Comparison:
The KOWA Portable Slit Lamp SL-14 was chosen as a substantially equivalent device. The predicate device is a hand-held slit lamp and is equipped with rechargeable battery. Similar to the predicate device the KOWA SL-15 is equipped with a rechargeable battery.

The KOWA SL-15 has the following similarities to those of the predicate device:
- has the same indicated use,
- uses the same operating principle,
- incorporates the same basic optical design,
- incorporates the similar materials,
- incorporates the similar light source.

The only modifications that were made are:
- Change the battery to Lithium-ion rechargeable battery from.

- Modify the charging circuit for Lithium-ion battery.
- Modify the power unit to switching regulator.
- Modify lamp bulb to 7.5V/15W Halogen lamp from 7.2V/15W Halogen lamp.

The comparison tables of KOWA SL-15 and KOWA Portable Slit Lamp SL-14 are shown in Table 4-1 and 4-2.

In summary, the KOWA SL-15 described in this submission is, in our opinion, substantially equivalent to the predicate device.

Conclusion:
KOWA SL-15 is equipped with the same fundamental technology features equivalent to the predicate devices, and also delivers the equivalent level safety and effectiveness. Thus it is concluded that there is no significant difference in the basic functions, safety and effectiveness between KOWA SL-15 and the predicate device.

Table A: Predicate device

Predicate Device	Manufacturer	510(k) No.	Date Cleared
KOWA Portable Slit Lamp SL-14	Kowa Company, Ltd.	K954782	Nov.24, 1995

Table B Predicate device comparison

	KOWA SL-15	KOWA Portable Slit Lamp SL-14
Indications For Use	Same	KOWA Portable Slit Lamp SL-14 is an ophthalmic device indicated for non-invasive illumination, magnification and observation of the human eye. It consists of a hand-held, battery powered slit-lamp biomicroscope with viewing and illumination optical systems and an AC-powered stand.
Microscope		
Angle of convergence	Same	13 degree
Magnification	Same	10X / 16X
Retiles	Same	Built-in both oculars
Magnification change	Same	16X and 10X Magnification is changed through movement of objectives to two positions.
Range of interpupillary distance adjustment	Same	50mm to 70mm
Range of examiner's dioptric protection adjustment.	Same	-8D to +4D

Table C Predicate Device Comparison

	KOWA SL-15	KOWA Portable Slit Lamp SL-14
Slit projection unit		
Slit selection	Same	Turret
Slit length	Same	12mm Fixed
Slit width	Same	0.1, 0.2, 0.8mm and ϕ12 spot
Light Intensity selection	Three selection: Full, 1/4 and 1/16	Three selection: Full, 1/2 and 1/4
Slit projection angle	Same	60 degree for Horizontal
Filter	Same	Built-in blue filter
Light source	7.5V, 15W Halogen lamp	7.2V, 15W Halogen lamp
Duration of illumination	Approximately 40 minutes	Approximately 20 minutes
Electric rating	DC 8.4V, 15W (Lithium-ion rechargeable battery)	DC 9V, 15W
Dimensions		
Power unit		
Type and electric rating	Same	Charger / Slit lamp stand
Input voltage	AC 100-240V, 50/60Hz	AC 100/117/220/240V Selected 50/60Hz
Power consumption	90VA	70VA
Compliance with safety standards		
EMC	IEC60601-1-2: 2001	-
Safety	IEC60601-1: 1988	-
Dimension		
Microscope		
Size	221mm(W)x106mm(D)x214mm(H)	95mm(W)x214mm(D)x213mm(H)
Weight	790g	900g
Power unit		
Size	124mm(W)x253mm(D)x68mm(H)	Type A: 190mm(W)x250mm(D)x125mm(H) Type B: 150mm(W)x250mm(D)x97mm(H)
Weight	1.25kg	Type A: 3.5kg Type B: 2.5kg

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

KOWA Company, Ltd.
c/o Satohiko Takanashi, PE, Chief Analyst
4-14, Nihonbashi-Honcho 3-chome
Chuo-ku, Tokyo, 103-8433 Japan

DEC 18 2006

Re: K063640
Trade/Device Name: Kowa SL-15 Slit Lamp
Regulation Number: 21 CFR 886.1850
Regulation Name: AC-powered slit lamp biomicroscope
Regulatory Class: Class II
Product Code: HJO
Dated: December 6, 2006
Received: December 7, 2006

Dear Mr. Takanashi:

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 Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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,

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 know): K063640

Device Name: KOWA SL-15

Indications for Use:

KOWA SL-15 is an ophthalmic device indicated for non-invasive illumination, magnification and observation of the human eye. It consists of a hand-held, battery powered slit-lamp biomicroscope with viewing and illumination optical systems and an AC-powered stand.

Prescription Use ✓ (Part 21 CFR 801 Subpart D) AND/OR

Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device

12/15/06

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

510(k) Number K063640