APR - 4 2008

K080681

**9. Certification**
**9.1 Summary for public disclosure**

**Submitter information:**


| | |
|---|---|
| Applicant: | Kowa Company, Ltd.<br>4-14, Nihonbashi-honcho 3-Chome<br>Chuo-ku, Tokyo, 103-8433 Japan<br>Phone: +81-3-5623-8063<br>Fax: +81-3-5623-8060 |
| Contact: | Satohiko Takanashi, PE |
| E-mail address: | s-takana@kowa.co.jp |
| Date summary prepared: | March 7, 2008 |


**Device identification:**

| | |
|---|---|
| Device trade name: | KOWA GENESIS-D |
| Classification name: | CAMERA, OPTHALMIC, AC-POWERED |
| Product code: | HKI |

**Intended use:**
The KOWA hand-held retinal camera, KOWA GENESIS-D is a device intended to capture and save fundus images with mydriatic.

**Comparison:**
The KOWA GENESIS-D was chosen as a substantially equivalent device. This modification is addition of optional goods for the predicate device. The predicate device is equipped with a highly sensitive CCD camera, does not require film for photography, and allows for immediate viewing of the image after image is captured.

The KOWA GENESIS-D and indirect diagnostic lens holder with lens 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 without the lens holder and lens,
- incorporates the same materials,
- incorporates the same power supply parts and circuits,
- incorporates the same light source,
- is packaged.

The only modification that was made is addition of the indirect diagnostic lens holder as an optional goods for the predicate device.

The comparison table of the predicate device and it with the indirect diagnostic lens holder is shown in Table B.

In summary, the predicate device with the indirect diagnostic lens holder described in this submission is substantially equivalent to the predicate device.

**Conclusion:**
The KOWA GENESIS-D and the indirect diagnostic lens holder with lens are equipped with the same fundamental technology and maintain the same level of safety performance. Therefore it has been concluded that there are no significant differences in the technological characteristics and safety of KOWA GENESIS-D that were cleared by addition the indirect diagnostic lens holder with lens.

**Table A: Predicate device**

| Predicate Device | Manufacturer | 510(k) No. | Date Cleared |
|---|---|---|---|
| KOWA GENESIS-D | Kowa Company, Ltd. | K0530271 | Nov.3, 2005 |

**Table B. Predicate device comparison**

| | KOWA GENESIS-D and indirect diagnostic lens holder, K9L-LH51 | KOWA GENESIS-D |
|---|---|---|
| **Intended use** | Same | A hand-held mydriatic retinal camera which captures fundus image. |
| **Use condition** | Same | with mydriatic |
| **Picture angle** | Same | Horizontal: 30 degree<br>Vertical: 25 degree |
| **Working distance** | Same | 5mm |
| **Observation** | Same | Visual observation |
| **Storage media** | Same | Flash memory card |
| **Camera spec.** | Same | Color CCD camera<br>2,000,000 pixels |
| **Image data format** | Same | JPEG and uncompressed format |
| **Diopter compensation** | Same | −15D～+35D |
| **Observation Light Source** | Same | Visible LED<br>4VA(approx. 1W) |
| **Photographing Light Source** | Same | Xenon flash lamp<br>23WS |
| **Optional goods** | Indirect diagnostic parts,<br>K9L-LH51 | Not applicable |
| **Power consumption** | Same | 60VA |
| **Weight of Camera unit** | Same | approx. 1kg |

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR - 4 2008

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

Re: K080681
Trade/Device Name: Kowa Genesis-D
Regulation Number: 21 CFR 886.1120
Regulation Name: Ophthalmic Camera
Regulatory Class: Class II
Product Code: HKI
Dated: March 7, 2008
Received: March 10, 2008

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 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,

Malvina B. Eydelman, M.D.

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): K080681

Device Name: KOWA GENESIS-D

Indications for Use:

The KOWA hand-held retinal camera, KOWA GENESIS-D is a device intended to capture and save fundus images with mydriatic.

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

3/25/2008

(Division Sign-Off)
Division of Ophthalmic Ear, Nose and Throat Devises
510(k) Number K080681