K073190

HUVITZ Co., Ltd.

JAN 1 1 2008

510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of 21 CFR Part 807.92

Date: Oct. 01, 2006

JAN 1 1 2008

1. Company and Correspondent making the submission:

Name – HUVITZ Co., Ltd.

Address – 689-3, Geumjeong-dong, Gunpo-si, Gyeonggi-do, 435-862, Republic of Korea

Telephone – +82-31-428-9100

Fax – +82-31-477-8617

Contact – Chang-Soo, Lee / QA Assistant Manager

E-mail – cslee@huvitz.com

2. Device :

Trade/proprietary name	: Slit Lamp HS-5000
Common Name	: Slit Lamp
Classification Name	: AC-Powered Slitlamp Biomicroscope

3. Predicate Devices :

Manufacturer	: C.S.O.S.R.L.
Device	: SL 990
510(k) Number	: K992836(Decision Date - Nov. 9, 1999)

4. Classifications Names & Citations :

21CFR 886.1850, HJO - AC-Powered Slitlamp Biomicroscope, Class 2

5. Description :

5.1 General

A slit lamp biomicroscope is intended for use in eye examination of the anterior eye segment, from the cornea epithelium to the posterior capsule. It is used to aid in the diagnosis of diseases or trauma which affect the structural properties of the anterior eye

segment.

These devices are designed for use by ophthalmologists and optometrists (within the realms of their respective professions) for specific diagnostic procedures (bio-microscopic examination of the eye)

5.2 Operation method

- Let the patient sit down comfortable with his chin on the chin-rest and his forehead against the forehead-rest
- Lift or lower the chin-rest by moving the handle (25) so that the patient s eyes are in line with the notches on the chin-rest (29)
- Switch the instruments on, press the switch (13). You will see the warning light on (12).
- Adjust the luminous intensity by moving the selector (14)
- Frame and focus the eye to be examined by moving the lever (9)

5.3 Operation Principles

The instrument is consist of a microscope, a swivelling illumination system providing a slit image and a power supply

- AC Power is converted to DC Power through the SMPS.
- DC Power is supplied to the Lamp providing the light
- Light is converted to the slit image through the aperture, filter etc.
- The slit image is illuminate the eye
- Observe the eye through the microscope

6. Indication for use :

The SLIT LAMP, HS-5000 is intended for use in eye examination of the anterior eye segment, from the cornea epithelium to the posterior capsule. It is used to aid in the diagnosis of diseases or trauma which affect the structural properties of the anterior eye segment.

7. Comparison with predicate device :

HUVITZ Co., Ltd. believes that the Slit Lamp, HS-5000 is substantially equivalent to Slit lamp SL 990 of C.S.O.S.R.L..

8. Safety, EMC and Performance Data :

Electrical, mechanical, and environmental safety testing according to Standard IEC

60601-1 was performed by UL Korea, Ltd. EMC testing was conducted by EMC Compliance Co., Ltd. in accordance with Standard IEC 60601-1-2(2001). All test results were satisfactory.

9. Conclusions :

In accordance with the Federal Food, Drug and Cosmetic Act, 21 CFR Part 807 and based on the information provided in this premarket notification HUVITZ Co., Ltd. concludes that the Slit Lamp, HS-5000 is safe and effective and substantially equivalent to predicate devices as described herein.

10. HUVITZ Co., Ltd. will update and include in this summary any other information deemed seasonably necessary by the FDA.

END

689-3 Geumjeong-dong Gunpo-si Gyeonggi-do 435-862 Republic of Korea

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 11 2008

Huvitz Co., Ltd.
c/o Charles F. Mack
International Regulatory Consultants
340 Shady Grove Road
Flintville, TN 37335

Re: K073190
Trade/Device Name: Slit Lamp HS-5000
Regulation Number: 21 CFR 886.1850
Regulation Name: AC-powered slitlamp microscope
Regulatory Class: Class II
Product Code: HJO
Dated: December 26, 2007
Received: December 28, 2007

Dear Mr. Mack:

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.
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: Slit Lamp HS-5000

Indications for Use:

The SLIT LAMP, HS-5000 is intended for use in eye examination of the anterior eye segment, from the cornea epithelium to the posterior capsule. It is used to aid in the diagnosis of diseases or trauma which affect the structural properties of the anterior eye segment.

Prescription Use V AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (Part 21 CFR 807 Subpart C)

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

Bruce Drum

Concurrence of CDRH, Office of Device Evaluation(ODE)

(Division Sign-Off)
Division of Ophthalmic Ear, Nose and Throat Devises
510(k) Number K073190

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