

AUG 14 1998

510 (k)#: K982057

Haag-Streit AG  
Gartenstadtstrasse 10  
CH-3098 Köniz / Bern  
  
Téléfon 031 971 46 55 / 56  
Fax 031 971 97 73

FDA, Center for Devices  
and Radiological Health  
Document Mail Centre (HFZ-401)  
9200 Corporate Blvd.  
Rockville, Maryland 20850 / USA

UU/mg

Köniz, May 13, 1998

Owner/Operator ID No. 8010098

### 510 (k) Summary

This summary of 510 (k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR § 807.92.

1. The submitter of this pre-market notification is:

Dr. Gerd Ulbers, Director R & D  
Haag-Streit AG  
Gartenstadtstrasse 10  
CH-3098 Köniz-Berne  
Telephone: +41 31 9714655  
Fax: +41 31 9719773

This summary was prepared on May 13, 1998.

2. The name of the device is the Haag-Streit BC 900 Slit Lamp. Its common name is the slit lamp and the classification name is the AC-powered slit lamp biomicroscope.
3. The BC 900 device is substantially equivalent to the Haag-Streit brand slit lamp 900® BM.
4. The Haag-Streit brand BC 900 slit lamp is an instrument used for eye examination and the fitting of contact lenses. The device consists of a microscope combined with a light source that can be narrowed into a slit for illumination of the eye. Each is available with accessories to measure characteristics of the eye and to document actual shapes. The device is powered by 7 to 12V AC and 50-60 Hz.
5. The device and accessories are indicated as a noninvasive aid in the examination and diagnosis of eye conditions and in the fitting of contact lenses. The indications are the same as those claimed for the predicate devices.
6. The technological characteristics are the same or similar to those found with the predicate devices where the eye is examined by projecting light onto it. Additionally, standard accessories are used for tonometry, examining the vitreous and fundus of the eye and contact lens fitting as those claimed for the predicate devices.



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

AUG 14 1998

Dr. Gerd Ulbers  
Director, Research and Development  
Haag - Streit AG  
Gartenstadtstrasse 10  
CH- 3098 Köniz - Berne  
Switzerland

Re: K982057  
Trade Name: BC 900 Slit Lamp  
Regulatory Class: II  
Product Code: 86 HJO  
Dated: May 13, 1998  
Received: June 11, 1998

Dear Dr. Ulbers:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,



A. Ralph Rosenthal, M.D.  
Director  
Division of Ophthalmic Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

## APPENDIX 3

Haag-Streit AG  
Gartenstadtstrasse 10  
CH-3098 Köniz / Bern

Telefon 031 971 46 55 / 56  
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Owner/Operator ID No. 8010098                      UL/mg                      Köniz, July 24, 1998

**510(K) Number (if known)**                      :                      Not yet allocated  
**Device Name**    :                      BC 900 Slit Lamp

**Indications for Use**

An AC-powered slit lamp biomicroscope is intended for use in eye examination of the anterior eye segment, from the corneal epithelium to the posterior capsule. It is used in the fitting of contact lenses and to aid in the diagnosis of diseases or trauma which affect the structural properties or topographic features of the anterior eye segment.

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

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*John C. Callaway*  
Concurrent of CDRI, Office of Device Evaluation (ODE)  
(Division Sign-Off)

Division of Ophthalmic Devices

510(k) Number     K982057    

Prescription Use .....  .....                      OR                      Over-the-Counter Use .....

(Per 21 CFR 801.109)