



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 26 2004

HAI Laboratories, Inc.
c/o Mr. Richard C. Lanzillotto
30 Northpoint Road
South Beach, NY 117891

Re: K994340

Trade/Device Name: Clinical Specular Microscope, Model HAI CL-1000xyz
Regulation Number: CFR 886.1850
Regulation Name: AC-powered slitlamp biomicroscope
Regulatory Class: Class II
Product Code: NQE
Dated: September 20, 2000
Received: December 23, 1999

Dear Mr. Lanzillotto:

This letter updates our substantially equivalent letter of September 20, 2000 regarding the product code and classification regulation of your device. Specular microscopes are now regulated under §886.1850 (AC-powered slitlamp biomicroscope) and are listed under a new product code (NQE). This letter is for informational purposes. No further action is required on your part at this time.

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 (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 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.

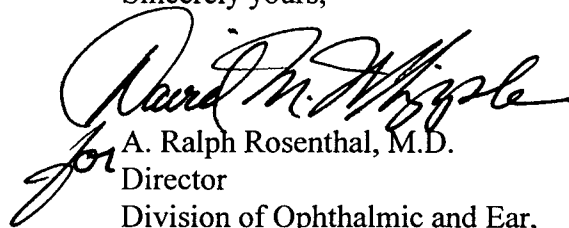
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

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 continue 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 and additionally Part 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. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at their toll free number (800) 638-2041 or at (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "A. Ralph Rosenthal". The signature is fluid and cursive, with a large initial "A" and "R".

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

Enclosure

HAI Laboratories, Inc.
HAI CL-1000xyz

Abbreviated 510K
12/21/99

INDICATIONS FOR USE

510(k) Number (if known):

Device Name: Clinical Specular Microscope
Model HAI CL-1000xyz

Indications for Use: The Clinical Specular Microscope Model HAI CL-1000xyz is intended to be used to examine the cornea of the eye.

Contraindications:
Warnings and
Precautions

CAUTION "Federal Law restricts this device to sale by or on the order of a physician or practitioner"

Also, see attached.

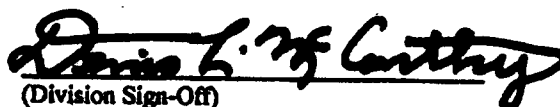
(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____


(Division Sign-Off)

Division of Ophthalmic Devices

510(k) Number K994340