SEP 2 5 2003

K030393

510(k) Summary
OLCR PACHYMETER: Pachy - 01 SL

General Information:

- Submitter's Name and Address:
  Rene Ott, Managing Director
  Haag-Streit AG
  Gartenstadtstrasse 10
  Koeniz, Bern, Switzerland CH-3098

- Contact Name:
  Eduardo March, Senior Consultant
  AAC Consulting Group Inc.
  7361 Calhoun Place, Suite 500
  Rockville, MD 20855
  Phone- 301.838.3120 Fax- 301.838-.3182

Trade Name:	Optical Low Coherence Reflectometry (OLCR) Pachymeter : Pachy-01 SL
Regulatory Class:	Class II
Product Code:	86 MXK, Device, analysis, anterior segment
Regulation:	21 CFR 886.1850, AC-powered slit-lamp biomicroscope

Device Description:
The Haag-Streit OLCR Pachymeter Pachy-01 SL is a device used with slit-lamp biomicroscopes to measure corneal thickness without eye contact. The Pachymeter is an add-on to Haag-Streit slit-lamps, including the BC 900, and those of other manufacturers marketed in the US. The Haag-Streit slit lamp and pachymeter provide ophthalmology specialists with the means of performing ocular measurements without contact, anesthesia, and external indentation of the ocular surface. The Haag-Streit pachymeter system allows for instantaneous, precise/reproducible and real time measurements.

The OLCR Pachymeter consists of a base unit, a light-delivery instrument and a user touch pad. The Pachymeter's Base unit generates a computer-controlled laser/light signal that is delivered through a fiber-optic coupler cable and emitted from a light-delivery instrument attached to the slit-lamp biomicroscope. The instrument emits light in the visible and infrared spectral regions within limit values specified by the ISO standard for ophthalmic instruments, ISO EN 15004. The instrument provides two laser exit locations; a location for the axial aiming laser and the measuring laser and a location for the lower aiming laser. The OLCR Pachymeter functions and assessment are user-controlled by means of a touch screen pad.

Intended Use:
The OLCR Pachy-01 SL is a device used with slit-lamp systems to measure corneal thickness. The OLCR Pachymeter includes the functional capability to perform

calculations of residual stroma thickness and correction to intraocular pressure values from user input.

Substantial Equivalence:
The OLCR Pachymeter when used with a slit-lamp biomicroscope is substantially equivalent, generally, to ultrasound diagnostic ophthalmic instruments used to image the anterior eye segment, perform calculations and estimate anterior chamber depth, axial length measurements and corneal radius and thickness.

The OLCR Pachymeter is, specifically, substantially equivalent to the IOLMaster from Carl Zeiss Inc. (K993357) and the Documenting Laser Slit Lamp from Bausch & Lomb Inc. (K012873). The OLCR Pachymeter is substantially equivalent to the IOLMaster, Zeiss, because both use light technology to provide ocular measurements and perform calculations needed to allow an ophthalmology specialist to evaluate the patient's eye.

Haag-Streit's Pachymeter is a class II medical device using a class I laser light source that emits light in the visible and infrared spectral regions and is subject to the Performance Standard for Light-emitting Products, 21 CFR Part 1040.10. The OLCR Pachymeter's performance conforms to the voluntary standard (IEC EN 60825-1) for class I laser devices. The IEC 60825 standard has been recognized by FDA as a means of meeting many of the part 1004.10 requirements for laser products.

The equivalence, accuracy and precision of the OLCR are demonstrated by nonclinical and clinical studies. In lab tests with 5 different biomicroscope slit lamp systems and with 9 pachymeters, Haag-Streit demonstrated the OLCR Pachymeter's accuracy and precision by mounting the pachymeters on different slit lamps to measure the thickness of an accepted calibration standard and glass check rods. In clinical studies, Haag-Streit has demonstrated the in-vivo precision or reproducibility of 5 OLCR pachymeters mounted on five different slit lamps to measure the central corneal thickness of 3 healthy individuals over 5 consecutive measurements. The measured accuracies of the 9 pachymeters in the lab and in-vivo studies have documented the accuracy under laboratory conditions and precision or variability of in-vivo human measurements with the OLCR Pachymeter.

The nonclinical and clinical tests demonstrate the OLCR Pachymeter is substantially equivalent to the IOLMaster system and other diagnostic ultrasound system used to measure corneal thickness.

Date Prepared: 9 Sept. 2003

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 2 5 2003

Haag-Streit International
C/O Eduardo March
Senior Consultant
AAC Consulting Group
7361 Calhoun Place, Suite 500
Rockville, MD 20855

Re: K030393
Trade Name: Optical Low Coherence Reflectometry (OLCR) Pachymeter, Pachy-01
Regulation: 21CFR 886.1850
Regulation Name: AC-powered slitlamp biomicroscope
Regulatory Class: Class II
Product Code: MXK
Dated: September 9, 2003
Received: September 9, 2003

Dear Mr. March:

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 (301) 594-4613. 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 (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

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

INDICATIONS FOR USE

510(K) NUMBER (If known): K030393

Device Name: OLCR PACHYMETER : PACHY-01 SL

Indications for Use:

The OLCR Pachymeter Pachy-01 SL is a device used with slit-lamp systems to measure corneal thickness. The OLCR Pachy-01 SL includes the functional capability to perform calculations of residual stroma thickness and correction to intraocular pressure values from user input.

(Division Sign-Off)
Division of Ophthalmic Ear,
Nose and Throat Devises
510(k) Number K030393 9-12-2003

(Please do not write below this line – Continue on other page if necessary)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-the Counter Use _____
(Per 21 CFR 801.109)