DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 2 9 2007

Carl Zeiss, Inc.
c/o Mr. Kenneth M. Nicoll
1 Zeiss Drive
Thornwood, NY 10594

Re: K961171
Trade/Device Name: Humphrey Optical Coherence Tomography (OCT) Scanner
Regulation Number: 21 CFR 886.1570
Regulation Name: Ophthalmoscope
Regulatory Class: II
Product Code: OBO
Dated: Unknown
Received: March 25, 1996

Dear Mr. Nicoll:

This letter updates our substantially equivalent letter of June 21, 1996.

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), please contact the Office of Compliance at (240) 276-0115. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Evenette M Beers PhD

for 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

K961171

JUN 21 1996

510-k Summary

Pursuant to 21 CFR 807.92 the following summary is submitted.

1. Submitter's name-
   Carl Zeiss, Inc.
   1 Zeiss Drive
   Thornwood, NY 10594
   (914) 681-7761
   Contact Person-Kenneth M. Nicoll
   March 21, 1996

2. Humphrey OCT (Optical Coherence Tomography) Scanner
   Optical Coherence Tomography Scanner

3. We are claiming substantial equivalence to the OCT predicate device, which already has market clearance.

4. In order to properly understand the Humphrey version of Optical Coherence Tomography Scanners you must understand how an Optical Coherence Tomography Scanner works. In general OCT Scanners permit the user to obtain and analyze cross-sectional tomograms of ocular tissue in a non-contact and non-invasive manner. The Humphrey Optical Coherence Tomography Scanner measures optical reflectivity to obtain cross sectional tomograms of the eye.

The Humphrey OCT employs the principle of low coherence interferometry based upon the Michelson interferometer. In a Michelson interferometer, the light from a source is split into a sample path and a reference path containing a mirror. Light reflected back from the sample path and the reference path will create an interference pattern on a detector if the optical path lengths between the reference and sample are identical. Adjusting the length of the reference path will allow a semi-transparent sample, such as the retina, to be cross-sectionally scanned.

The Super-Luminescent Diode (SLD) used in the Humphrey OCT Scanner permits a short coherence length in air. Accounting for the index of refraction of the eye, this translates to an even shorter coherence length within the retina. The SLD emits near infrared light which is scattered by the various interfaces and structures of the retinal tissue. As the reference arm is moved, a depth profile of the retina is produced which is similar to ultrasound A-scan. The profile plots variations in optical reflectivity between the different layers of the retina. Two mirrors mounted to galvanometers deflect the SLD beam within the eye. Scanning the retina in this manner produces cross-sectional images similar to ultrasound B-scan but of much higher resolution. The tomographic images of the retina produced by the OCT scanner provide an important tool in the diagnosis of retinal disorders and diseases that manifest themselves in the posterior pole of the eye.

5. This device will be used in the same manner as all OCT scanner devices are used for two dimensional cross-sectional imaging of the posterior segment of the eye. It incorporates the original intended uses of our earlier claimed substantially equivalent products. It is used primarily for diagnosing and monitoring retinal diseases and disorders that manifest themselves in the posterior pole of the eye. Clinical studies with the OCT have demonstrated its effectiveness in detecting and quantifying the extent of macular edema, macular holes, retinal detachments and central serious chorioretinopathy.

6. The modified OCT is substantially equivalent to the predicate device. One of the differences between the two devices are that the new OCT combines many of the separate components which were utilized into one more cohesive unit. The two devices are very similar in materials and energy source. The primary differences between the two are the way the exteriors are designed and their appearance. The new OCT has a redesigned delivery system. This improvement permits a greater field of view, a longer working distance, the introduction of the Landmark system and a new internal fixation system.

Clinical studies were mentioned above.