K013110

510(k) SUMMARY

Culemborg,
October 28, 2001

DEC 1 9 2001

1. **Submitter information**
   Gerard de Wit, Ph. D.
   Optical diagnostics
   Eikvaren 19
   4102 XE Culemborg
   The Netherlands
   Tel. (+31) 345- 518116

2. **Device name**
   The Aniseikonia Inspector

3. **Substantial equivalence**
   The device basically is a haploscope (886.1340) used to detect and manage aniseikonia.

4. **Description of the device**
   The device is based on an old technique called 'direct comparison eikonometry'. I.e. the two eyes are offered a different image and the subject needs to determine if there is a size imbalance between the two images. If there is an imbalance in size, the size of one of the images is changed until the subject perceives the two images as equal in size. The extent in which one of the images needed to be changed in size is a measure for the amount of aniseikonia of the subject.

   In The Aniseikonia Inspector the separation between the two eyes is accomplished by holding a red and a green filter in front of the eyes. The images are created on a computer screen and they can be altered by using a computer periheral such as the keyboard.

5. **Intended use**
   The device is designed to detect and quantify the amount of aniseikonia of a patient. Aniseikonia is defined as a condition of binocular vision where there is a relative difference in the size and/or shape of the ocular image of the two eyes. If a significant amount of aniseikonia is detected in a patient, a new prescription (contact lenses and/or glasses) can be calculated to reduce the amount of aniseikonia.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 1 9 2001

Optical Diagnostics, Inc.
c/o Ms. Joyce De Wit
Eikvaren 19
4102 XE Culemborg
The Netherlands

Re: K013110
Trade/Device Name: The Aniseikonia Inspector
Regulation Number: 21 CFR 886.1340
Regulation Name: Haploscope
Regulatory Class: I
Product Code: HJT
Dated: October 31, 2001
Received: November 13, 2001

Dear Ms. De Wit:

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 and additionally 21 CFR 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. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained 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

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

510(k) Number (if known): **K013110**

Device Name: **The Aniseikonia Inspector**

Indications For Use:

This device is intended to assist in the detection and management of aniseikonia.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Quynh Hoang Scientific Reviewer

(Division Sign-Off)
Division of Ophthalmic Ear,
Nose and Throat Devises

510(k) Number K013110

(Optional Format 3-10-98)