DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV - 2 2000

Mr. Kevin Walls, RAC
President
Regulatory Associates, Incorporated
777 S. Wadsworth Blvd.
Bldg. 2, Ste. 102
Lakewood, Colorado 80226

Re: K003236
Trade Name: RetinaDx Digital Angiography System (Camera Ophthalmic)
Regulatory Class: II
Product Code: 86 HKI
Regulation: 886.1120
Dated: October 16, 2000
Received: October 17, 2000

Dear Mr. Walls:

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) 594-6413. 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 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/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): K003236

Device Name: RetinaDx Digital Angiography System

Indications for Use: The RetinaDx Angiography System is intended for use by trained medical professionals (physicians, ophthalmic technicians, ophthalmic photographers or others with similar training) in a medical office, hospital or other medical setting. It is indicated when a medical professional suspects a patient could have damage or disease of the retina. It is used to take photographs of the patient's retina, which are then studied by the medical professional to get additional information about the retina to consider in his or her efforts to decide on a diagnosis and treatment plan. The RetinaDx system can be used with any patient of any age or condition who is able to sit still enough to have the photographs taken.

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

Denis L. McCarthy

(Division Sign-Off)
Division of Ophthalmic Devices

510(k) Number K003236

Prescription Use X OR **Over-The-Counter Use** ___
(Per 21 CFR 801.109) (Optional Format 1-2-96)