DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 15 1999

Brys C. Myers
Manager, Regulatory Affairs
INOVA Diagnostics, Inc.
10180 Scripps Ranch Boulevard
San Diego, CA 92131-1234

Re: K984222
Trade Name: QUANTA Lite™ Lyme *B. burgdorferi* IgG ELISA
Regulatory Class: II
Product Code: LSR
Dated: February 5, 1999
Received: February 9, 1999

Dear Mr. Myers:

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 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). 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.

Under the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88), this device may require a CLIA complexity categorization. To determine if it does, you should contact the Centers for Disease Control and Prevention (CDC) at (770)488-7655.

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) 594-4588. 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" (21 CFR 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 at (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html"

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K984222

Device Name: QUANTA Lite™ Lyme *B. burgdorferi* IgG ELISA

Indications For Use:

The QUANTA Lite™ Lyme *B. burgdorferi* IgG ELISA kit is an enzyme-linked immunosorbent assay (ELISA) for the initial (first-step) qualitative detection of IgG antibodies to *B. burgdorferi*, the agent of Lyme disease (Lyme borreliosis), in human serum. This ELISA is intended to provide presumptive evidence of the presence of antibodies to *B. burgdorferi*. Equivocal or positive results should be followed by a standardized second-step supplemental procedure such as Western blot assays. Positive results on a second-step assay can support a clinical diagnosis of Lyme disease. Diagnosis of Lyme disease should be based on history, physical findings, and other laboratory data in addition to anti-*B. burgdorferi* results. Negative results should not be the sole basis for exclusion of *B. burgdorferi* infection.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Woody Dubois

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K984222

Prescription Use X **OR** **Over-The-Counter Use** ____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)