



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
2098 Gaither Road  
Rockville MD 20850

INOVA Diagnostics, Inc.  
c/o Gary L. Norman, Ph.D.  
Senior Scientist  
9900 Old Grove Rd  
San Diego, CA 92131-1638

**OCT 27 2008**

Re: k081248

Trade/Device Name: QUANTA Lite™ OMP Plus IgA ELISA

Regulation Number: 21 CFR 866.5785

Regulation Name: Anti-Saccharomyces cerevisiae (*S. Cerevisiae*) antibody (ASCA) test system

Regulatory Class: Class II

Product Code: OKM

Dated: September 25, 2008

Received: September 25, 2008

Dear Dr. Norman:

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). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The

Page 2 – Gary L. Norman, PhD

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 information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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/industry/support/index.html>.

Sincerely yours,



Maria M. Chan, Ph.D.  
Acting Director  
Division of Immunology and Hematology Devices  
Office of In Vitro Diagnostic Device Evaluation and Safety  
Center for Devices and Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known): K081248

Device Name: QUANTA Lite™ OMP Plus ELISA

Indications for Use:

The QUANTA Lite™ OMP Plus kit is an enzyme-linked immunosorbent assay (ELISA) for the semi-quantitative detection of anti-OMP antibodies of the IgA class in human serum. It is intended to be used in conjunction with anti-*Saccharomyces cerevisiae* (*S. cerevisiae*) antibody (ASCA) IgG and/or IgA test systems. The presence of OMP (outer membrane proteins) IgA antibodies, used in conjunction with clinical findings and other laboratory tests, may aid in the diagnosis of patients with Crohn's disease.

Prescription Use   x    
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use \_\_\_\_\_  
(21 CFR 807 Subpart C)

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

---

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

*Maria M Chan*

Division Sign-Off

Office of In Vitro Diagnostic  
Device Evaluation and Safety

510(k) K081248

Page 1 of   1