



JUN 13 2005

Food and Drug Administration  
2098 Gaither Road  
Rockville MD 20850

INOVA Diagnostics, Inc.  
c/o Dr. Gary L. Norman  
10180 Scripps Ranch Blvd.  
San Diego, CA 92131

Re: k050662

Trade/Device Name: QUANTA Lite™ sp100 ELISA  
Regulation Number: 21 CFR 866.5090  
Regulation Name: Antimitochondrial Antibody Immunological Test System  
Regulatory Class: Class II  
Product Code: NUM  
Dated: March 11, 2005  
Received: March 29, 2005

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); 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 legally

Page 2 – Dr. Gary L. Norman

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) 276-0131. 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 (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,



Robert L. Becker, Jr., M.D., PhD

Director

Division of Immunology and Hematology Devices

Office of In Vitro Diagnostic Device Evaluation and Safety

Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K050662

Device Name: QUANTA Lite™ sp100 ELISA

**Indications For Use:**

The QUANTA Lite™ sp100 kit is an enzyme-linked immunosorbent assay (ELISA) for the semi-quantitative detection of anti-sp100 antibody of the IgG class in human serum. This test is intended to aid in the diagnosis of primary biliary cirrhosis (PBC).

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

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**Concurrence of CDRH, Office of Device Evaluation (ODE)**

*Mona Chan*

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Division Sign-Off

Office of In Vitro Diagnostic Device  
Evaluation and Safety

510(k) K050662

Prescription Use X  
(Per 21 CFR 801.109)

OR

Over-The-Counter Use \_\_\_\_\_

(Optional Format 1-2-96)