



Food and Drug Administration  
10903 New Hampshire Avenue  
Silver Spring, MD 20993

INOVA Diagnostics, Inc.  
c/o Rufus Burlingame, Ph.D.  
Director, Technology and Development  
9900 Old Grove Road  
San Diego, CA 92131

**OCT 20 2011**

Re: k111414

Trade/Device Name: QUANTA Flash™ DGP Screen  
QUANTA Flash™ DGP Screen Calibrators  
QUANTA Flash™ DGP Screen Controls

Regulation Number: 21 CFR §866.5750

Regulation Name: Radioallergosorbent (RAST) Immunological Test System

Regulatory Class: Class II

Product Code: MST, JIX, JJX

Dated: September 19, 2011

Received: September 21, 2011

Dear Dr. Burlingame:

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 class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. 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 Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter

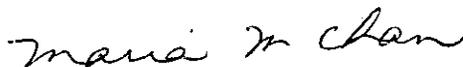
Page 2 – Rufus Burlingame, Ph.D.

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 Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Maria Chan, Ph.D.  
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): k111414

Device Name: QUANTA Flash™ DGP Screen

### Indications For Use:

The QUANTA Flash™ DGP Screen is a chemiluminescent immunoassay (CIA) for the semi-quantitative detection of IgG and IgA anti-deamidated gliadin peptide (DGP) antibodies in human serum on the BIO-FLASH® instrument. It is an aid in the diagnosis of celiac disease and dermatitis herpetiformis in conjunction with clinical findings and other laboratory tests.

Prescription Use   X    
(Part 21 CFR 801 Subpart D)

AND/OR

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

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

  
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Division Sign-Off

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Office of In Vitro Diagnostic  
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## Indications for Use

510(k) Number (if known): k111414

Device Name: QUANTA Flash™ DGP Screen Calibrators

### Indications For Use:

The QUANTA Flash™ DGP Screen Calibrators are intended for use with the QUANTA Flash™ DGP Screen chemiluminescent immunoassay (CIA) on the BIO-FLASH® instrument. Each calibrator establishes a point of reference for the working curve that is used to determine Chemiluminescent Unit (CU) values in the measurement of IgG and IgA anti-DGP antibodies in serum.

Prescription Use  X   
(Part 21 CFR 801 Subpart D)

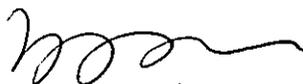
AND/OR

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

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## Indications for Use

510(k) Number (if known): k111414

Device Name: QUANTA Flash™ DGP Screen Controls

### Indications For Use:

The QUANTA Flash™ DGP Screen Controls are intended for quality control purposes of the QUANTA Flash™ DGP Screen chemiluminescent immunoassay (CIA) kit run on a BIO-FLASH® instrument.

Prescription Use  X   
(Part 21 CFR 801 Subpart D)

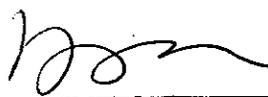
AND/OR

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

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