DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration

10903 New Hampshire Avenue
Silver Spring, MD 20993

Inova Diagnostics, Inc.
c/o Rosanna Keivens
9900 Old Grove Rd.
San Diego, California 92131-1638

JUL 3 1 2012

Re: k112545
Trade/Device Name:
QUANTA Flash® PR3 Reagents
QUANTA Flash® PR3 Calibrators
QUANTA Flash® PR3 Controls

QUANTA Flash® MPO Reagents
QUANTA Flash® MPO Calibrators
QUANTA Flash® MPO Controls

QUANTA Flash® GBM Reagents
QUANTA Flash® GBM Calibrators
QUANTA Flash® GBM Controls

Regulation Number: 21 CFR §866.5660
Regulation Name: Multiple Autoantibodies Immunological Test System
Regulatory Class: Class II
Product Code: MOB, MVJ, JIX, JJX
Dated: June 20, 2012
Received: June 26, 2012

Dear Ms. Keivens:

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 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,

Reena Philip

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

Enclosure

Indications for Use Form

510(k) Number (if known): k112545

Device Name: QUANTA Flash® PR3 Reagents

Indications for Use:

The QUANTA Flash PR3 is a chemiluminescent immunoassay (CIA) for the semi-quantitative detection of IgG anti-proteinase 3 (PR3) autoantibodies in human serum on the BIO-FLASH® instrument. QUANTA Flash PR3 is an aid in the diagnosis of granulomatosis with polyangiitis (GPA) 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 801 Subpart C)

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

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

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K112545

Indications for Use Form

510(k) Number (if known): k112545

Device Name: QUANTA Flash® PR3 Calibrators

Indications for Use:

The QUANTA Flash PR3 Calibrators are intended for use with the QUANTA Flash PR3 chemiluminescent immunoassay (CIA) on the BIO-FLASH® instrument. Each calibrator establishes a point of reference for the working curve that is used in the measurement of IgG anti-proteinase 3 (PR3) autoantibodies in human serum.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

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Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) k112545

Indications for Use Form

510(k) Number (if known): k112545

Device Name: QUANTA Flash® PR3 Controls

Indications for Use:

The QUANTA Flash PR3 Controls are intended for quality control purposes of the QUANTA Flash PR3 chemiluminescent immunoassay (CIA) kit run on a BIO-FLASH® instrument that is used in the measurement of IgG anti-proteinase 3 (PR3) autoantibodies in human serum.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

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Evaluation and Safety

510(k) K112545

Indications for Use Form

510(k) Number (if known): k112545

Device Name: QUANTA Flash® MPO Reagents

Indications for Use:

The QUANTA Flash MPO is a chemiluminescent immunoassay (CIA) for the semi-quantitative detection of IgG anti-myeloperoxidase (MPO) autoantibodies in human serum on the BIO-FLASH® instrument. QUANTA Flash MPO is an aid in the diagnosis of microscopic polyangiitis (MPA) 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 801 Subpart C)

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Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K112545

Indications for Use Form

510(k) Number (if known): k112545

Device Name: QUANTA Flash® MPO Calibrators

Indications for Use:

The QUANTA Flash MPO Calibrators are intended for use with the QUANTA Flash MPO chemiluminescent immunoassay (CIA) on the BIO-FLASH® instrument. Each calibrator establishes a point of reference for the working curve that is used in the measurement of IgG anti-myeloperoxidase (MPO) autoantibodies in human serum.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

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510(k) K112545

Indications for Use Form

510(k) Number (if known): k112545

Device Name: QUANTA Flash® MPO Controls

Indications for Use:

The QUANTA Flash MPO Controls are intended for quality control purposes of the QUANTA Flash MPO chemiluminescent immunoassay (CIA) kit run on a BIO-FLASH® instrument that is used in the measurement of IgG anti-myeloperoxidase (MPO) autoantibodies in human serum.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

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510(k) K112545

Indications for Use Form

510(k) Number (if known): k112545

Device Name: QUANTA Flash® GBM Reagents

Indications for Use:

The QUANTA Flash GBM is a chemiluminescent immunoassay (CIA) for the semi-quantitative detection of IgG anti-glomerular basement membrane (GBM) autoantibodies in human serum on the BIO-FLASH® instrument. QUANTA Flash GBM is an aid in the diagnosis of Goodpasture's Syndrome 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 801 Subpart C)

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Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K112545

Indications for Use Form

510(k) Number (if known): k112545

Device Name: QUANTA Flash® GBM Calibrators

Indications for Use:

The QUANTA Flash GBM Calibrators are intended for use with the QUANTA Flash GBM chemiluminescent immunoassay (CIA) on the BIO-FLASH® instrument. Each calibrator establishes a point of reference for the working curve that is used in the measurement of IgG anti-glomerular basement membrane (GBM) autoantibodies in human serum.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

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510(k) K112545

Indications for Use Form

510(k) Number (if known): k112545

Device Name: QUANTA Flash® GBM Controls

Indications for Use:

The QUANTA Flash GBM Controls are intended for quality control purposes of the QUANTA Flash GBM chemiluminescent immunoassay (CIA) kit run on a BIO-FLASH® instrument that is used in the measurement of IgG anti-glomerular basement membrane (GBM) autoantibodies in human serum.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

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