DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

October 31, 2013

INOVA DIAGNOSTICS, INC.
C/O MS. ROSANNA KEIVENS
DIRECTOR OF QUALITY SYSTEMS
9900 OLD GROVE ROAD
SAN DIEGO, CA 92131

Re: k120817
Trade/Device Name: QUANTA Flash™ β2GP1 IgA
QUANTA Flash™ aCL IgA
QUANTA Flash™ β2GP1 IgA Controls
QUANTA Flash™ aCL IgA Controls
Regulation Number: 21 CFR 866.5660
Regulation Name: Multiple autoantibodies immunological test system
Regulatory Class: Class II
Product Code: MID, MSV, JJX
Dated: February 20, 2013
Received: February 21, 2013

Dear Ms. Keivens:

This letter corrects our substantially equivalent letter of February 26, 2013.

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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 Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact 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/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Reena Philip -S

for Maria M. Chan, Ph.D.
Director
Division of Immunology and Hematology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K120817

Device Name: QUANTA Flash™ aCL IgA

Indications For Use:
QUANTA Flash aCL IgA: Fully automated chemiluminescent immunoassay for the semi-quantitative measurement of anti-cardiolipin (aCL) IgA antibodies in human citrated plasma and serum on the BIO-FLASH® instrument, as an aid in the diagnosis of thrombotic disorders related to primary and secondary antiphospholipid syndrome (APS), when used in conjunction with other laboratory and clinical findings.

Device Name: QUANTA Flash™ aCL IgA Controls

Indications For Use:
The QUANTA Flash aCL IgA Controls are intended for quality control purposes of the QUANTA Flash aCL IgA assay performed on the BIO-FLASH® instrument.

Prescription Use __X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (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 Diagnostics and Radiological Health (OIR)

Reena Philip -S
2013.03.04 12:24:33 -05'00'

Indications for Use

510(k) Number (if known): K120817

Device Name: QUANTA Flash™ β2GP1 IgA

Indications For Use:
Fully automated chemiluminescent immunoassay for the semi-quantitative measurement of anti-β2 glycoprotein-1 (β2GP1) IgA antibodies in human citrated plasma and serum on the BIO-FLASH® instrument, as an aid in the diagnosis of thrombotic disorders related to primary and secondary antiphospholipid syndrome, when used in conjunction with other laboratory and clinical findings.

Device Name: QUANTA Flash™ β2GP1 IgA Controls

Indications For Use:
The QUANTA Flash β2GP1 IgA Controls are intended for the quality control purposes of the QUANTA Flash β2GP1 IgA assay performed on the BIO-FLASH® instrument.

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 Diagnostics and Radiological Health (OIR)

Reena Philip -S
2013.03.04 12:25:36 -05'00'