



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

May 7, 2013

INOVA Diagnostics Inc.
c/o Dr. Michael Mahler, Ph.D.
9900 Old Grove Road
San Diego, CA 92131

Re: k122923

Trade/Device Name: QUANTA Flash ENA7 Reagent Kit
QUANTA Flash ENA7 Calibrator Kit
QUANTA Flash ENA7 Control Kit
Regulation Number: 21 CFR §866.5100
Regulation Name: Antinuclear antibody immunological test system
Regulatory Class: Class II
Product Code: LLL, JIX, JJX
Dated: April 2, 2013
Received: April 5, 2013

Dear Dr. Mahler:

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 Part 801); 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 Part 801), 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 (OIR)

Center for Devices and Radiological Health

Enclosure

Indications for Use Form

510(k) Number (if known): k122923

Device Name: QUANTA Flash® ENA7 Reagents

Indications for Use:

QUANTA Flash ENA7 is a chemiluminescent immunoassay for the qualitative screening of IgG autoantibodies to Sm, RNP, Ro60 (SS-A), Ro52/TRIM21, SS-B (La), Scl-70 (topoisomerase I) and Jo-1 in human serum. The presence of these autoantibodies is used as an aid in the diagnosis of systemic lupus erythematosus (SLE), systemic sclerosis (SSc), polymyositis (PM), dermatomyositis (DM), sjogren's syndrome (SjS) and mixed connective tissue disease (MCTD) 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 Diagnostics and Radiological Health (OIR)

Reena Philip, -S

Division Sign-Off

Office of In Vitro Diagnostics and Radiological Health

510(k) k122923

Indications for Use Form

510(k) Number (if known): k122923

Device Name: QUANTA Flash® ENA7 Calibrator Kit

Indications for Use:

QUANTA Flash ENA7 Calibrators are intended for use with the QUANTA Flash ENA7 Reagents for the determination of IgG autoantibodies to Sm, RNP, Ro60 (SS-A), Ro52/TRIM21, SS-B (La), Scl-70 (topoisomerase I) and Jo-1 in human serum. Each calibrator establishes a point of reference for the working curve that is used to calculate the unit values.

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
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510(k) k122923

Indications for Use Form

510(k) Number (if known): k122923

Device Name: QUANTA Flash® ENA7 Control Kit

Indications for Use:

QUANTA Flash ENA7 Controls are intended for use with the QUANTA Flash ENA7 Reagents for quality control in the determination of IgG autoantibodies to Sm, RNP, Ro60 (SS-A), Ro52/TRIM21, SS-B (La), Scl-70 (topoisomerase I) and Jo-1 in human serum.

Prescription Use
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

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