



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

INOVA DIAGNOSTICS, INC.
C/O MS. ANDREA SEAMAN
SUPERVISOR, IMMUNOPATHOLOGY RESEARCH
9900 OLD GROVE RD.
SAN DIEGO CA 92131-1638

February 7, 2014

Re: k123880

Trade/Device Name: Quanta Flash Centromere Reagent
Quanta Flash Centromere Calibrators
Quanta Flash Centromere Controls

Regulation Number: 21 CFR 866.5100

Regulation Name: Antinuclear antibody immunological test system

Regulatory Class: II

Product Code: LJM, JIX, JJX

Dated: February 3, 2014

Received: February 4, 2014

Dear Ms. Seaman:

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 regulations (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" (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/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

Maria M. Chan -S

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)
k123880

Device Name
QUANTA Flash Centromere Reagent

Indications for Use (Describe)

QUANTA Flash Centromere is a chemiluminescent immunoassay for the semi-quantitative determination of IgG anti-centromere protein B autoantibodies in human serum. The presence of anti-centromere protein B autoantibodies is used as an aid in the diagnosis Systemic Sclerosis, in conjunction with clinical finding and other laboratory tests.

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

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

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FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) (Signature)

Elizabeth  Stafford -S

Indications for Use

510(k) Number (if known)
k123880

Device Name
QUANTA Flash Centromere Calibrators

Indications for Use (Describe)
QUANTA Flash Centromere Calibrators are intended for use with the QUANTA Flash Centromere Reagents for the determination of IgG anti-Centromere autoantibodies in human serum. Each calibrator establishes a point of reference for the working curve that is used to calculate the unit values.

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

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

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Indications for Use

510(k) Number (if known)
k123880

Device Name
QUANTA Flash Centromere Controls

Indications for Use (Describe)
QUANTA Flash Centromere Controls are intended for use with the QUANTA Flash Centromere Reagents for quality control in the determination of IgG anti-centromere protein B autoantibodies in human serum.

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

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

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