



Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-002

OCT 25 2012

IMMCO Diagnostics, Inc.
c/o Mr. Kevin J. Lawson
VP Regulatory Affairs
60 Pineview Drive,
Buffalo, NY 14228

Re: k113020

Trade/Device Name: ImmuLisa Enhanced™ Cardiolipin IgA Antibody (ACA) ELISA
ImmuLisa Enhanced™ Cardiolipin IgG Antibody (ACA) ELISA
ImmuLisa Enhanced™ Cardiolipin IgM Antibody (ACA) ELISA
ImmuLisa Enhanced™ Cardiolipin IgA/IgG/IgM Antibody (ACA)
ELISA

Regulation Number: 21 CFR §866.5660

Regulation Name: Multiple autoantibodies immunological test system

Regulatory Class: Class II

Product Code: MID

Dated: October 23, 2012

Received: October 24, 2012

Dear Mr. Lawson:

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.

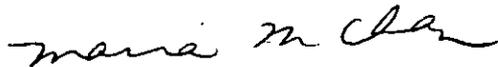
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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 go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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, Ph.D.
Director
Division 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): K113020

Device Name: ImmuLisa Enhanced™ Cardiolipin IgA Antibody (ACA)
ELISA

Indications For Use: Enzyme linked immunoassay (ELISA) for the qualitative or semi-quantitative detection of Cardiolipin IgA antibodies in human serum to aid in the diagnosis of antiphospholipid syndrome (APS) and APS associated with systemic lupus erythematosus (SLE) in conjunction with other laboratory tests and clinical findings.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(Part 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 Diagnostic Devices (OIVD)

NZP Nisar Panyon
Division Sign-Off

Office of In Vitro Diagnostic
Device Evaluation and Safety

510K K113020

Indications for Use

510(k) Number (if known): K113020

Device Name: ImmuLisa Enhanced™ Cardiolipin IgG Antibody (ACA)
ELISA

Indications For Use: Enzyme linked immunoassay (ELISA) for the qualitative or semi-quantitative detection of Cardiolipin IgG antibodies in human serum to aid in the diagnosis of antiphospholipid syndrome (APS) and APS associated with systemic lupus erythematosus (SLE) in conjunction with other laboratory tests and clinical findings.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(Part 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 Diagnostic Devices (OIVD)

NEP Nisa Pampur
Division Sign-Off

Office of In Vitro Diagnostic
Device Evaluation and Safety

510K K113020

Indications for Use

510(k) Number (if known): K113020

Device Name: ImmuLisa Enhanced™ Cardiolipin IgM Antibody (ACA)
ELISA

Indications For Use: Enzyme linked immunoassay (ELISA) for the qualitative or semi-quantitative detection of Cardiolipin IgM antibodies in human serum to aid in the diagnosis of antiphospholipid syndrome (APS) and APS associated with systemic lupus erythematosus (SLE) in conjunction with other laboratory tests and clinical findings.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(Part 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 Diagnostic Devices (OIVD)

NZP Nijar Pampani
Division Sign-Off

Office of In Vitro Diagnostic
Device Evaluation and Safety

510K K113020

Indications for Use

510(k) Number (if known): K113020

Device Name: ImmuLisa Enhanced™ Cardiolipin IgA/IgG/IgM Antibody (ACA) ELISA

Indications For Use: Enzyme linked immunoassay (ELISA) for the qualitative detection of Cardiolipin IgA, IgG and IgM antibodies in human serum to aid in the diagnosis of anti-phospholipid syndrome (APS) and APS associated with systemic lupus erythematosus (SLE) in conjunction with other laboratory tests and clinical findings.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(Part 21 CFR 807 Subpart C)

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

N2P Nisha Ramya
Division Sign-Off

Office of In Vitro Diagnostic
Device Evaluation and Safety

510K K113020