



Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

March 31, 2015

IMMCO DIAGNOSTICS, INC.
MR. KEVIN J. LAWSON
VICE PRESIDENT REGULATORY AFFAIRS
60 PINEVIEW DRIVE
BUFFALO, NY 14228

Re: k142781

Trade/Device Name:	ImmuLisa Enhanced™ SS-A (Ro) Antibody ELISA ImmuLisa Enhanced™ SS-B (La) Antibody ELISA ImmuLisa Enhanced™ Sm Antibody ELISA ImmuLisa Enhanced™ RNP Antibody ELISA
Regulation Number:	21 CFR §866.5100
Regulation Name:	Antinuclear antibody immunological test system
Regulatory Class:	Class II
Product Code:	LLL, LKP
Dated:	February 25, 2015
Received:	February 27, 2015

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 contact the Division of Industry and Consumer Education 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 Industry and Consumer Education 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,

Leonthena R. Carrington -A

Leonthena R. Carrington, MS, MBA, MT(ASCP)
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)

k142781

Device Name

ImmuLisa Enhanced™ SS-A (Ro) Antibody ELISA

Indications for Use (Describe)

Enzyme linked immunoassay (ELISA) for the qualitative and semi-quantitative detection of SS-A (Ro) (52 kD and 60 kD) IgG antibodies in human serum as an aid in diagnosis of Systemic Lupus Erythematosus (SLE) and Sjögren's Syndrome in conjunction with clinical findings 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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRASStaff@fda.hhs.gov

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Indications for Use

510(k) Number (if known)

k142781

Device Name

ImmuLisa Enhanced™ SS-B (La) Antibody ELISA

Indications for Use (Describe)

Enzyme linked immunoassay (ELISA) for the qualitative and semi-quantitative detection of SS-B (La) IgG antibodies in human serum as an aid in diagnosis of Systemic Lupus Erythematosus (SLE) and Sjögren's Syndrome in conjunction with clinical findings 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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Indications for Use

510(k) Number (if known)

k142781

Device Name

ImmuLisa Enhanced™ Sm Antibody ELISA

Indications for Use (Describe)

Enzyme linked immunoassay (ELISA) for the qualitative and semi-quantitative detection of Sm IgG antibodies in human serum as an aid in diagnosis of Systemic Lupus Erythematosus (SLE) in conjunction with clinical findings 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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Indications for Use

510(k) Number (if known)

k142781

Device Name

ImmuLisa Enhanced™ RNP Antibody ELISA

Indications for Use (Describe)

Enzyme linked immunoassay (ELISA) for the qualitative and semi-quantitative detection of RNP IgG antibodies in human serum as an aid in diagnosis of Systemic Lupus Erythematosus (SLE) and Mixed Connective Tissue Disease (MCTD) in conjunction with clinical findings 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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