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

IMMCO DIAGNOSTICS, INC.
Kevin Lawson
Vice President, Regulatory Affairs
9870 Hollingson Road
Clarence, NY 14031

June 19, 2017

Re: K162788
Trade/Device Name: ImmuLisa Enhanced B2GP1 IgA Antibody ELISA, ImmuLisa Enhanced B2GP1 IgG Antibody ELISA, ImmuLisa Enhanced B2GP1 IgM Antibody ELISA, ImmuLisa Enhanced B2GP1 IgA/IgG/IgM Antibody ELISA
Regulation Number: 21 CFR 866.5660
Regulation Name: Multiple autoantibodies immunological test system
Regulatory Class: II
Product Code: MSV
Dated: May 30, 2017
Received: May 31, 2017

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 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 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" (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 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,

Kelly Oliner -S

For,
Leonthena Carrington, MBA, MS, MT (ASCP)
Division Director
Division of Immunology and Hematology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K162788

Device Name

1. ImmuLisa Enhanced™ B2GP1 IgA Antibody ELISA. 2. ImmuLisa Enhanced™ B2GP1 IgG Antibody ELISA. 3. ImmuLisa Enhanced™ B2GP1 IgM Antibody ELISA. 4. ImmuLisa Enhanced™ B2GP1 IgA/IgG/IgM ELISA.

Indications for Use *(Describe)*

1. Enzyme-linked immunosorbent assay (ELISA) for the qualitative or semi-quantitative detection of β2-GPI IgA antibodies in human serum to aid in diagnosis of autoimmune thrombotic disorders associated with antiphospholipid syndrome (APS) and APS with systemic lupus erythematosus (SLE) in conjunction with other laboratory tests and clinical findings.
2. Enzyme-linked immunosorbent assay (ELISA) for the qualitative or semi-quantitative detection of β2-GPI IgG antibodies in human serum to aid in diagnosis of autoimmune thrombotic disorders associated with antiphospholipid syndrome (APS) and APS with systemic lupus erythematosus (SLE) in conjunction with other laboratory tests and clinical findings.
3. Enzyme-linked immunosorbent assay (ELISA) for the qualitative or semi-quantitative detection of β2-GPI IgM antibodies in human serum to aid in diagnosis of autoimmune thrombotic disorders associated with antiphospholipid syndrome (APS) and APS with systemic lupus erythematosus (SLE) in conjunction with other laboratory tests and clinical findings.
4. Enzyme-linked immunosorbent assay (ELISA) for the qualitative detection of β2-GPI IgA, IgG and IgM antibodies in human serum to aid in diagnosis of autoimmune thrombotic disorders associated with antiphospholipid syndrome (APS) and APS with systemic lupus erythematosus (SLE) in conjunction with other laboratory tests and clinical findings.

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.

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510(k) Summary

Submitter:	Immco Diagnostics, Inc.
Address:	60 Pineview Dr., Buffalo, NY 14228
Phone Number:	716-691-0091 ext. 110
Contact:	Kevin Lawson
Summary Prepared:	6-14-2017
Device Name:	ImmuLisa Enhanced™ B2GP1 IgA Antibody ELISA ImmuLisa Enhanced™ B2GP1 IgG Antibody ELISA ImmuLisa Enhanced™ B2GP1 IgM Antibody ELISA ImmuLisa Enhanced™ B2GP1 IgA/IgG/IgM Antibody ELISA
Common Name:	B2GP1 Antibody ELISA
Product Code:	MSV, system,test,antibodies,b2 - glycoprotein i (b2 - gpi)
Substantially Equivalent to:	INOVA QUANTA Lite™ β2 GPI IgA, IgG, IgM and Screen ELISAs

General Description: Antiphospholipid antibodies are a heterogeneous group of autoantibodies against negatively charged phospholipids.[1] They are detected primarily by the anti-cardiolipin antibody (ACA) test, the biological false positive test for syphilis or the lupus anticoagulant test. These three tests detect related, but not necessarily identical antibodies. Thus, more than one of these tests may be necessary to identify antiphospholipid antibodies.

Of the various tests for the detection of antiphospholipid antibodies, the anti-cardiolipin antibody test performed by ELISA is the most sensitive.[2] The presence of anti-cardiolipin antibodies helps to identify patients at risk of venous and/or arterial thrombosis often accompanied by thrombocytopenia, a syndrome referred to as antiphospholipid syndrome.[1-12] It most commonly occurs in patients with systemic lupus erythematosus (SLE) or lupus-like diseases where the criteria for SLE are not fulfilled.[5-7] High levels of anti-cardiolipin antibodies occur in thrombosis, fetal loss, thrombocytopenia and several other disorders.[1-15] Anti-cardiolipin antibodies are routinely detected by ELISA, using cardiolipin as the antigen. Recent observations have indicated that 50kD serum factor is necessary for ACA to bind to cardiolipin. This co-factor was later identified as beta 2 glycoprotein 1 (B2GP1) or synonymously apolipoprotein H.[16-18] Though the function of B2GP1 remains unclear, it is certain that the presence of B2GP1 facilitates the binding of the ACA to cardiolipin. Anti-cardiolipin antibodies, especially at low levels are found in a variety of clinical disorders unrelated to anti-phospholipid syndrome. ACA present in sera of patients with SLE and other autoimmune disorders are immunologically distinct from sera of patients with syphilis. The use of B2GP1 protein as a replacement for cardiolipin antigen on the solid matrix helps to make this distinction. Furthermore, anti-B2GP1 antibodies are very specific for anti-phospholipid syndrome

The test is performed as a solid phase immunoassay (ELISA) in B2GP1 coated microwells. Controls, Calibrators and patient serum samples are incubated in the antigen coated microwells to allow antibodies present in the serum to bind. Unbound antibody and other serum proteins are removed by washing the microwells. Antibodies bound to the microwells are detected by adding an enzyme labeled anti-human IgA, IgG, IgM or IgA/IgG/IgM conjugate to the microwells. These enzyme conjugated antibodies bind specifically to the human immunoglobulin of the appropriate class. Unbound enzyme-labeled conjugate is removed by washing. Specific enzyme substrate (TMB) is then added to the wells and the presence of antibodies is detected by a color change produced by the conversion of the TMB substrate. The reaction is stopped and the intensity of color change, which is proportional to the concentration of antibody, is read by a spectrophotometer at 450 nm. Results are expressed in ELISA units per milliliter (EU/ml).

Intended Use: ImmuLisa Enhanced™ B2GP1 IgA Antibody ELISA: Enzyme-linked immunosorbent assay (ELISA) for the qualitative or semi-quantitative detection of β2-GPI IgA antibodies in human serum to aid in diagnosis of autoimmune thrombotic disorders associated with antiphospholipid syndrome (APS) and APS with systemic lupus erythematosus (SLE) in conjunction with other laboratory tests and clinical findings.

ImmuLisa Enhanced™ B2GP1 IgA/IgG/IGM Antibody ELISA: Enzyme-linked immunosorbent assay (ELISA) for the qualitative detection of β2-GPI IgA, IgG and IgM antibodies in human serum to aid in diagnosis of autoimmune thrombotic disorders associated with

antiphospholipid syndrome (APS) and APS with systemic lupus erythematosus (SLE) in conjunction with other laboratory tests and clinical findings.

ImmuLisa Enhanced™ B2GP1 IgM Antibody ELISA: Enzyme-linked immunosorbent assay (ELISA) for the qualitative or semi-quantitative detection of β2-GPI IgM antibodies in human serum to aid in diagnosis of autoimmune thrombotic disorders associated with antiphospholipid syndrome (APS) and APS with systemic lupus erythematosus (SLE) in conjunction with other laboratory tests and clinical findings.

ImmuLisa Enhanced™ B2GP1 IgG Antibody ELISA: Enzyme-linked immunosorbent assay (ELISA) for the qualitative or semi-quantitative detection of β2-GPI IgG antibodies in human serum to aid in diagnosis of autoimmune thrombotic disorders associated with antiphospholipid syndrome (APS) and APS with systemic lupus erythematosus (SLE) in conjunction with other laboratory tests and clinical findings.

Similarities and Differences: Both sets of kits detect antibodies to beta 2 glycoprotein 1antigen coated on 96 well plates to detect with HRP anti-human IgG conjugate and TMB substrate. Both sets of IgA, IgG and IgM kits utilize a 5 point calibrator curve, however, Immco uses a borderline/indeterminate range of 20-25EU/ml, while INOVA does not use a borderline/indeterminate range. The Immco IgA/IgG/IGM kit uses a single calibrator set at 30EU/ml, has a cutoff of 20 units with no borderline range and incorporates a combined IgA/IgG/IgM conjugate.

Non-clinical Tests:

Method Comparison: Both kits were tested with APS subjects and disease controls.

IMMCO IgA Method Comparison Study 2x2 Table

borderline considered positive

		Other B2GP1 IgA ELISA		
		Pos	Neg	Total
IMMCO B2GP1 IgA ELISA	Pos	86	2	88
	Neg	29	211	240
	Total	115	213	328

Pos % Agreement	74.8%	(95% CI 65.7% - 82.2%)
Neg % Agreement	99.1%	(95% CI 96.3% - 99.8%)
Overall % Agree	90.5%	(95% CI 86.7% - 93.4%)

IMMCO IgG Method Comparison Study 2x2 Table

borderline considered positive

		Other B2GP1 IgG ELISA		
		Pos	Neg	Total
IMMCO B2GP1 IgG ELISA	Pos	64	21	85
	Neg	13	240	253
	Total	77	261	338

Pos % Agreement	83.1%	(95% CI 72.5% - 90.4%)
Neg % Agreement	92.0%	(95% CI 87.8% - 94.8%)
Overall % Agree	89.9%	(95% CI 86.2% - 92.8%)

IMMCO IgM Method Comparison Study 2x2 Table

borderline considered positive

		Other B2GP1 IgM ELISA		
		Pos	Neg	Total
IMMCO	Pos	110	2	112
B2GP1 IgM	Neg	10	233	243
ELISA	Total	120	235	355

Pos % Agreement	91.7%	(95% CI 84.8% - 95.7%)
Neg % Agreement	99.1%	(95% CI 96.7% - 99.9%)
Overall % Agree	96.6%	(95% CI 94.3% - 98.4%)

IMMCO IgA/G/M Method Comparison Study 2x2 Table

		Other IgA/G/M specific isotype ELISA		
		Any Pos	All Neg	Total
IMMCO	Pos	142	5	147
B2GP1	Neg	35	149	184
A/G/M ELISA	Total	177	154	331

Pos % Agreement	80.2%	(95% CI 73.4% - 85.7%)
Neg % Agreement	96.8%	(95% CI 92.2% - 98.8%)
Overall % Agree	87.9%	(95% CI 83.8% - 91.1%)

Cross Reactivity:

Potentially co-incident antibody positive or cross-reactive specimens selected from individuals suffering from other autoimmune or infectious diseases were tested for B2GP1 antibodies using the ImmuLisa™ assay. Indeterminate samples were considered positive.

B2GP1 Abs	IgA			IgG			IgM		
Condition	n	n Pos	% Pos	n	n Pos	% Pos	n	n Pos	% Pos
Syphilis	40	7	17.5%	40	3	7.5%	40	5	12.5%
HCV	32	0	0.0%	32	3	9.4%	32	1	3.1%
Celiac	16	0	0.0%	0	0	0.0%	0	0	0.0%
Polymyositis	17	3	17.6%	17	0	0.0%	17	1	5.9%
Dermatomyositis	12	2	16.7%	12	0	0.0%	12	1	8.3%
RA	46	6	13.0%	60	4	6.7%	60	0	0.0%
Systemic Sclerosis	31	3	9.7%	23	3	13.0%	23	1	4.3%
Sjögren's	37	2	5.4%	37	5	13.5%	37	2	5.4%
Stroke	15	1	6.7%	15	0	0.0%	15	1	6.7%
Epilepsy	14	1	7.1%	14	0	0.0%	14	1	7.1%
Arterial Thrombosis	15	1	6.7%	15	2	13.3%	15	1	6.7%
Venous Thrombosis	15	0	0.0%	15	0	0.0%	15	0	0.0%
Myocardial Infarction	20	3	15.0%	20	0	0.0%	20	1	5.0%
Acute Coronary Syndrome	10	1	10.0%	10	0	0.0%	10	0	0.0%
Pre-eclampsia	20	0	0.0%	20	3	15.0%	20	0	0.0%
SNHL	0	0	0.0%	10	0	0.0%	0	0	0.0%
Hashimoto's	7	0	0.0%	20	0	0.0%	20	0	0.0%
Graves	25	3	12.0%	18	1	5.6%	18	0	0.0%
Wegener's	45	4	8.9%	34	0	0.0%	34	1	2.9%

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Churg-Strauss	23	3	13.0%	23	1	4.3%	23	0	0.0%
Crohn's	20	0	0.0%	20	1	5.0%	20	0	0.0%
Ulcerative Colitis	20	1	5.0%	20	2	10.0%	20	2	10.0%
Toxoplasma	10	0	0.0%	10	1	10.0%	10	1	10.0%
CMV	10	0	0.0%	10	1	10.0%	10	1	10.0%
Rubella	10	0	0.0%	10	0	0.0%	10	0	0.0%

B2GP1 Abs IgA/IgG/IgM

Condition	n	n Pos	% Pos
Syphilis	37	8	21.6%
HCV	32	2	6.3%
Celiac	22	1	4.5%
Polymyositis	17	2	11.8%
Dermatomyositis	12	0	0.0%
RA	45	3	6.7%
Systemic Sclerosis	23	2	8.7%
Sjögren's	37	2	5.4%
Stroke	15	1	6.7%
Epilepsy	14	1	7.1%
Arterial Thrombosis	15	3	20.0%
Venous Thrombosis	15	1	6.7%
Myocardial Infarction	20	4	20.0%
Acute Coronary Syndrome	10	1	10.0%
Pre-eclampsia	20	0	0.0%
SNHL	7	0	0.0%
Hashimoto's	7	0	0.0%
Graves	20	1	5.0%
Wegener's	42	1	2.4%
Churg-Strauss	23	2	8.7%
Crohn's	20	1	5.0%
Ulcerative Colitis	20	2	10.0%
Toxoplasma	10	1	10.0%
CMV	10	2	20.0%
Rubella	10	0	0.0%

Interference

Interference was studied by mixing sera with known B2GP1 levels for each assay with potentially interfering serum samples and studying deviation from expected results. No significant interference was demonstrated for the following substances at the levels indicated: Hemoglobin (2 g/L), Bilirubin (342 µmol/L), Rheumatoid Factor (100 EU/ml), Triglycerides (37 mmol/L), Cholesterol (13 mmol/L), Heparin (3000 U/L), Acetylsalicylic Acid (3.62 mmol/L), Prednisone (0.84 µmol/L), Warfarin (32.5 µmol/L), Hydroxychloroquine (148 µmol/L), Rituximab (75 µg/ml), and Atorvastatin (600 µg EQ/L).

Precision

Precision was tested with positive specimens selected throughout the range of the assay. Seven patients were run in 13 assays with 6 replicates of each sample over a period of 4 weeks. An additional assay of 12 replicates was run to determine repeatability (n=90 replicates per sample). Assays were run by two operators on two different sets of equipment.

S#	Mean EU/ml	Total Imprecision SD	Total Imprecision CV%	Between days SD	Between days CV%	Between Operator SD	Between Operator CV%	Within run (Repeatability) SD	Within run (Repeatability) CV%
1	8.5	0.5	6.0	0.3	3.3	0.2	2.8	0.3	4.1
2	16.4	1.1	7.0	0.8	5.2	0.6	3.6	0.5	3.0
3	20.4	1.1	5.6	0.5	2.3	0.5	2.5	0.9	4.4
4	23.8	1.1	4.6	0.8	3.5	0.5	2.2	0.5	1.9
5	49.0	3.1	6.2	2.2	4.5	1.5	3.1	1.5	3.0
6	105.1	4.0	3.8	2.7	2.6	2.4	2.3	1.7	1.6
7	150.6	5.3	3.5	2.0	1.4	2.8	1.9	4.0	2.7

Reproducibility

Qualitative reproducibility was tested with 90 replicates of samples in the negative range, ~20% below cutoff, ~20% above cutoff, in the moderate positive range of the assay and near the cutoff using the qualitative analysis method. Samples were tested by two different operators / equipment sets. The cutoff samples produced 76.7% (positive), 76.7% (positive) and 61.1% (negative) qualitative agreement for IgA, IgG and IgM, respectively. Results for the IgM cutoff – 20% specimen produced 96.7% (negative) qualitative agreement. Assay results for all other specimens produced 100% qualitative agreement. For the IgA/IgG/IgM assay results of the ~20% below cutoff specimen produced 97.8% qualitative agreement (negative). The cutoff sample produced 50% positive and 50% negative qualitative agreement. Results for all other specimens produced 100% qualitative agreement.

Limit of Detection

The limits of detection (LoD) for these assays were determined to be 3.6 EU/ml for IgA, 3.1 EU/ml for IgG , 2.3 EU/ml for IgM, and 2.7 EU/ml for IgA/IgG/IgM based on 60 replicates of the blank and 10 replicates each of 5 low-level (normal blood donor) samples. .

Linearity and Recovery

For the individual IgA, IgG and IgM kits, linearity and recovery were tested by diluting positive specimens through the assay range in equidistant dilutions and comparing actual vs. expected results. The linear range of the IgA assay was determined to be 3.6–160 EU/ml. The linear range of the IgG assay was determined to be 3.1–160 EU/ml. The linear range of the IgM assay was determined to be 2.3–160 EU/ml. Results are summarized below:

Test Range (EU/ml)	Slope (95% CI)	Y-intercept (95% CI)	R^2	% recovery (obtained/expected)
B2GP1 IgA				
2.3 to 17.8	1.06 (0.89 to 1.21)	-0.59 (-2.4 to 1.2)	0.9767	88% to 112%
11.0 to 63.9	1.05 (0.97 to 1.14)	-0.77 (-4.2 to 2.6)	0.9934	93% to 105%
59.0 to 168.3	1.08 (0.94 to 1.22)	-0.68 (-16.7 to 15.4)	0.9915	90% to 100%
B2GP1 IgG				
2.1 to 41.4	1.04 (0.89 to 1.19)	0.2 (-1.8 to 4.9))	0.9807	82% to 100%
4.1 to 140.9	1.03 (0.93 to 1.13)	4.13 (-3.9 to 12.1)	0.9905	86% to 100%
3.3 to 198.1	0.99 (0.91 to 1.07)	7.25 (-1.8 to 16.3)	0.9936	82% to 100%
B2GP1 IgM				
1.7 to 63.4	1.00 (0.95 to 1.05)	1.8 (-0.1 to 3.6)	0.9974	81% to 100%
5.4 to 87.5	1.02 (0.93 to 1.10)	2.3 (-1.9 to 6.4)	0.9936	89% to 100%
54.7 to 173.5	0.96 (0.82 to 1.09)	3.1 (-13.1 to 19.4)	0.9963	86% to 110%

To assess hook effect, dilutions of high positive specimens with results above the 160 EU/ml measuring range were tested. Hook effect was not demonstrated in dilution samples as high as 228.6 EU/ml for IgA, 597.6 EU/ml for IgG, and 605.5 EU/ml for IgM testing within OD range of the microplate reader (~3.5OD).

Clinical Tests: Sets of clinical samples were tested to assess sensitivity and specificity for APS, APS with SLE and SLE. Results are summarized below.

	B2GP1 IgA % (95%CI)		B2GP1 IgG % (95%CI)		B2GP1 IgM% (95%CI)		B2GP1 IgA/IgG/IgM% (95%CI)	
Disease	Sensitivity	Specificity	Sensitivity	Specificity	Sensitivity	Specificity	Sensitivity	Specificity
APS	38.3 (30.0-47.3)	92.0 (89.3-94.1)	58.8 (48.3-68.5)	93.8 (91.3-95.7)	64.1 (55.7-71.8)	96.1 (93.9-97.5)	84.8% (76.1-90.8)	91.9% (89.1-94.0)
APS with SLE	19.4 (12.5-28.6)	92.0 (89.3-94.1)	57.7 (48.5-66.5)	93.8 (91.3-95.7)	46.5 (36.5-56.7)	96.1 (93.9-97.5)	66.0% (55.8-75.0)	91.9% (89.1-94.0)
SLE	10.9 (4.9-21.8)	92.0 (89.3-94.1)	26.5 (18.4-36.6)	93.8 (91.3-95.7)	18.8 (12.0-28.1)	96.1 (93.9-97.5)	24.6% (14.8-37.6)	91.9% (89.1-94.0)

* Sensitivity/specificity exclude healthy human blood donors and cases submitted for reference laboratory testing with a possible diagnosis of APS or SLE. Borderline results are considered positive.

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VP Regulatory Affairs

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