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

February 1, 2017

Immco Diagnostics, Inc.
Kevin Lawson
Regulatory Officer
60 Pineview Dr.
Buffalo, New York 14031

Re: K163095
Trade/Device Name: Lyme *B. Burgdorferi* (IgG) MarStripe Test
Regulation Number: 21 CFR 866.3830
Regulation Name: Treponema pallidum treponemal test reagents
Regulatory Class: Class II
Product Code: LSR
Dated: September 10, 2016
Received: November 4, 2016

Dear Kevin 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 and Part 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 regulation (21 CFR Part 801 and Part 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,

Steven R. Gitterman -S

Uwe Scherf, Ph.D.
Director
Division of Microbiology 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)*

K163095

Device Name

Lyme *B. burgdorferi* (IgG) MarStripe Test

Indications for Use *(Describe)*

Lyme *B. burgdorferi* (IgG) MarStripe Test is an immunoblot assay for the *in vitro* qualitative detection of human IgG antibody to individual proteins of *Borrelia burgdorferi* in human serum or plasma (K_2-EDTA) in samples which have been found positive or equivocal using an EIA or IFA test procedure to provide supportive evidence of infection with *B. burgdorferi*.

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 of Safety and Effectiveness

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirement of SMDA 1990 and 21 CFR 807.92.

1. **Submitter Name:** Immco Diagnostics, Inc. a Trinity Biotech Company
   Address: 60 Pineview Dr., Buffalo, NY 14228
   Phone Number: 716-691-0091 ext. 110
   Contact Person: Kevin Lawson
   Summary Prepared: 1-4-2017

2. **Device Name:** Lyme *B. burgdorferi* (IgG) MarStripe Test
   Common Name: Lyme *B. burgdorferi* (IgG) Immunoblot
   Product Code: LSR

3. **Substantially equivalent to:** MarDx *B. burgdorferi* IgG MarBlot Strip Test System (K950829)

4. **Description of device:** The kit is an immunoblot method to detect IgG antibodies against *B. burgdorferi* antigens. The test kit contains:
   - Nitrocellulose Test Strips with purified *B. burgdorferi* antigens (10) and quality control lines (3) present in specific positions
   - Sample Diluent. Provided for specimen dilutions. Contains BSA and PBS
   - Positive Control derived from human serum positive for Lyme disease. Contains <0.1% sodium azide
   - Negative Control derived from human serum negative for Lyme disease. Contains <0.1% sodium azide
   - Conjugate. Antihuman IgG-HRP Conjugate binds reactive antibodies to the Substrate
   - TMB Substrate. Provides colorimetric reaction for visual read of bound antibodies
   - PBS Wash Buffer concentrate. Removes reagents and unbound antibodies after incubation steps. Must be reconstituted to 1L with distilled or deionized water.

   To perform the test, serum or plasma is incubated with individual *B. burgdorferi* Test Strips. In positive sera antibodies specifically bind to one or more of the test lines on the strip. The strips are washed according to the protocol, and then the pre-diluted, ready-to-use Conjugate is added to the test strips. After incubation and wash steps, the ready-to-use Substrate is added to the strips. During a 10 minute (±4 min) incubation, conjugate and substrate binding produces visible blue/purple lines for Serum Addition Control (SAC), Conjugate Addition Control (CAC) and Cut-Off Control lines. If the sample is positive for any of the antigen coated test lines, it will show a reaction more intense than the Cut-Off line. Reactions are read visually and reported as positive, negative or equivocal (comparable to Cut-Off line). Strips which have 5 (or more) of the 10 test lines are considered positive for specific IgG antibody *to B. burgdorferi*.

5. **Intended Use:** Lyme *B. burgdorferi* (IgG) MarStripe Test is an immunoblot assay for the in vitro qualitative detection of human IgG antibody to individual proteins of *Borrelia burgdorferi* in human serum or plasma (K_2- EDTA) in samples which have been found positive or equivocal using an EIA or IFA test procedure to provide supportive evidence of infection with *B. burgdorferi*.

6. **Similarities and Differences:** The Lyme *B. burgdorferi* (IgG) MarStripe Test was compared to a commercially marketed kit by Trinity Biotech the *B. burgdorferi* (IgG) MarBlot Strip Test System (K950829). Both kits have the same intended use and use the same methodology except that the MarStripe Test has been validated in plasma (K_2- EDTA) as well as serum. Both immunoblot kits detect antibodies to *B. burgdorferi* antigens using the standard immunoblot IgG algorithm. Both assays are qualitative. The MarStripe uses a Horseradish Peroxidase Conjugate and Tetramethylbenzidine (TMB) Substrate/Chromogen in comparison to The MarBlot Alkaline Phosphatase Conjugate and BCIP/NBT Substrate/Chromogen. The MarStripe uses a Cutoff Control line incorporated in the strip in comparison to the 41kD band of Weakly Reactive Control.

7. **Non-clinical Tests:**

Reproducibility

Eight specimens were tested by Lyme *B. burgdorferi* (IgG) MarStripe Test in 4 replicates, two runs per day over 9 days for a total of 72 tests for each specimen at three laboratory sites. Results were read by 2 human operators at each site, equaling a total of 432 read-outs. Samples were selected based on FDA cleared *B. burgdorferi* ELISA results, including 2 low negative samples, 2 high negative samples, 2 low positive samples and 2 moderate positive samples. Final positive or negative agreement was 100% for all specimens.

Sample		p93	p66	p58	p45	p41	p39	p30	p28	p23	p18
1	n=432										
	Low Neg	Neg.	Neg.	Neg.	Neg.	Neg.	Neg.	Neg.	Neg.	Neg.	Neg.
	Band Type	0	0	0	0	0	0	0	0	0	0
	Positives	432	432	432	432	432	432	432	432	432	432
	Negatives	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%
2	% Positive										
	Low Neg	Neg.	Neg.	Neg.	Neg.	Pos.	Neg.	Neg.	Neg.	Neg.	Neg.
	Band Type	0	0	0	0	432	0	0	0	0	0
	Positives	432	432	432	432	0	432	432	432	432	432
	Negatives	0%	0%	0%	0%	100%	0%	0%	0%	0%	0%
3	% Positive										
	High Neg	Neg.	Neg.	Neg.	Neg.	Neg.	Neg.	Neg.	Neg.	Neg.	Neg.
	Band Type	0	0	0	0	0	0	0	0	0	0
	Positives	432	432	432	432	432	432	432	432	432	432
	Negatives	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%
4	% Positive										
	High Neg	Neg.	Neg.	Neg.	Neg.	Pos.	Neg.	Neg.	Neg.	Neg.	Neg.
	Band Type	0	0	0	0	432	0	0	0	0	0
	Positives	432	432	432	432	0	432	432	432	432	432
	Negatives	0%	0%	0%	0%	100%	0%	0%	0%	0%	0%
5	% Positive										
	Low Pos	Neg.	Neg.	Neg.	Neg.	Pos.	Neg.	Neg.	Neg.	Pos.	Neg.
	Band Type	0	0	0	0	432	0	0	0	432	0
	Positives	432	432	432	432	0	432	432	432	0	432
	Negatives	0%	0%	0%	0%	100%	0%	0%	0%	100%	0%
6	% Positive										
	Low Pos	Neg.	Neg.	Neg.	Neg.	Pos.	Neg.	Neg.	Neg.	Pos.	Neg.
	Band Type	0	0	0	0	432	0	0	0	432	0
	Positives	432	432	432	432	0	432	432	432	0	432
	Negatives	0%	0%	0%	0%	100%	0%	0%	0%	100%	0%
7	% Positive										
	Moderate Pos	Wpos.	Pos.	Pos.	Neg.	Pos.	Pos.	Cut.	Pos.	Pos.	Pos.
	Band Type	412	432	432	0	432	432	412	432	432	432
	Positives	20	0	0	432	0	0	20	0	0	0
	Negatives	95%	100%	100%	0%	100%	100%	95%	100%	100%	100%
8	% Positive										
	Moderate Pos	Pos.	Neg.	Pos.	Neg.	Pos.	Pos.	Neg.	Neg.	Pos.	Neg.
	Band Type	432	0	432	0	432	432	0	0	432	0
	Positives	0	432	0	432	0	0	432	432	0	432
	Negatives	100%	0%	100%	0%	100%	100%	0%	0%	100%	0%
	% Positive										

Pos = positive band. Neg = negative band. Wpos = weak positive band. Cut = equivocal band.

Analytical Specificity: 219 sera from healthy blood donors representing endemic and non-endemic geographic regions of the United States were tested. Analytical specificity was determined to be 99.5% (95% CI: 97.1% - 100%).

		Normal Individuals
Lyme IgG MarStripe Test	Positive	1
	Negative	218
	Total	219

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Cross-reactivity: A total of 136 potentially cross-reactive specimens from individuals with other autoimmune disorders or infectious conditions were tested on this assay. Positive incidence was 4.4% and all positives specimens by the Lyme *B. burgdorferi* (IgG) MarStripe Test were confirmed positive when tested by the predicate IgG Western blot device.

Population	n	n Positive	% Positive
Ehrlichia chafeensis	10	0	0
Babesia microti	10	4	40
Leptospira interrogans	10	0	0
Helicobacter pylori	10	2	20
Syphilis	10	0	0
Influenza	10	0	0
Rocky Mountain Spotted Fever	10	0	0
Parvovirus B19	9	0	0
Systemic lupus erythematosus	15	0	0
Cytomegalovirus	10	0	0
Rheumatoid arthritis	16	0	0
Celiac	16	0	0
Total	136	6	4.4

Interference: Two Lyme IgG negative and three Lyme IgG positive sera were spiked with hemoglobin (2g/L), unconjugated bilirubin (342 µmol/L), RF (100 IU/ml), triglycerides (3.7 mmol/L) and total cholesterol (13 mmol/L) and tested using this assay. Samples were tested with and without interfering agents. Qualitative agreement was 100% for all specimens.

Serum vs. Plasma Matrix Comparison Studies: To establish equivalence of serum vs. plasma (K_2-EDTA) matrix, 10 pairs of sera/plasma (samples A-J below) were sourced from specimens tested on an FDA cleared Lyme EIA assay. Two of these were Western blot IgG positive, 8 were negative. These specimens were selectively pooled to create another set of 10 samples (samples 1-10 below), including 3 Western blot IgG positives and 7 negatives. These samples were assayed on the Lyme *B. burgdorferi* (IgG) MarStripe Test. Qualitative agreement for all pairs was 100%.

Sample ID[1]	Type[2]	p93	p66	p58	p45	p41	p39	p30	p28	p23	p18	Result	Band % Pos Agrmt	Band % Neg Agrmt
A	Serum	0	0	0	0	1	0	0	0	1	0	NEG	100	100
A	Plasma	0	0	0	0	1	0	0	0	1	0	NEG		
B	Serum	0	0	0	0	0	0	0	0	0	0	NEG	100	100
B	Plasma	0	0	0	0	0	0	0	0	0	0	NEG		
C	Serum	1	0	1	0	1	1	1	0	1	1	POS	100	100
C	Plasma	1	0	1	0	1	1	1	0	1	1	POS		
D	Serum	0	0	1	0	1	1	1	0	1	1	POS	100	100
D	Plasma	0	0	1	0	1	1	1	0	1	1	POS		
E	Serum	0	0	0	0	0	0	0	0	0	1	NEG	100	100
E	Plasma	0	0	0	0	0	0	0	0	0	1	NEG		
F	Serum	0	0	0	0	0	0	0	0	0	0	NEG	100	100
F	Plasma	0	0	0	0	0	0	0	0	0	0	NEG		
G	Serum	0	0	0	0	0	0	0	0	0	0	NEG	100	100
G	Plasma	0	0	0	0	0	0	0	0	0	0	NEG		
H	Serum	0	0	0	0	0	0	0	0	0	0	NEG	100	100
H	Plasma	0	0	0	0	0	0	0	0	0	0	NEG		
I	Serum	0	0	0	0	0	0	0	0	0	0	NEG	100	100
I	Plasma	0	0	0	0	0	0	0	0	0	0	NEG		
J	Serum	0	0	0	0	0	0	0	0	0	0	NEG	100	100
J	Plasma	0	0	0	0	0	0	0	0	0	0	NEG		
Pool 1 (A+B)	Serum	0	0	0	0	0	0	0	0	1	0	NEG	100	100
Pool 1 (A+B)	Plasma	0	0	0	0	0	0	0	0	1	0	NEG		
Pool 2 (B+C)	Serum	1	0	1	0	1	1	0	0	1	1	POS	100	100
Pool 2 (B+C)	Plasma	1	0	1	0	1	1	0	0	1	1	POS		
Pool 3 (C+D)	Serum	1	0	1	0	1	1	1	0	1	1	POS	100	100
Pool 3 (C+D)	Plasma	1	0	1	0	1	1	1	0	1	1	POS		
Pool 4 (D+E)	Serum	0	0	1	0	1	1	0	0	1	1	POS	100	100
Pool 4 (D+E)	Plasma	0	0	1	0	1	1	0	0	1	1	POS		
Pool 5 (A+E)	Serum	0	0	0	0	1	0	0	0	1	0	NEG	100	100
Pool 5 (A+E)	Plasma	0	0	0	0	1	0	0	0	1	0	NEG		
Pool 6 (F+G)	Serum	0	0	0	0	0	0	0	0	0	0	NEG	100	100
Pool 6 (F+G)	Plasma	0	0	0	0	0	0	0	0	0	0	NEG		
Pool 7 (G+H)	Serum	0	0	0	0	0	0	0	0	0	0	NEG	100	100
Pool 7 (G+H)	Plasma	0	0	0	0	0	0	0	0	0	0	NEG		
Pool 8 (H+I)	Serum	0	0	0	0	0	0	0	0	0	0	NEG	100	100
Pool 8 (H+I)	Plasma	0	0	0	0	0	0	0	0	0	0	NEG		
Pool 9 (I+J)	Serum	0	0	0	0	0	0	0	0	0	0	NEG	100	100
Pool 9 (I+J)	Plasma	0	0	0	0	0	0	0	0	0	0	NEG		
Pool 10 (F+J)	Serum	0	0	0	0	0	0	0	0	0	0	NEG	100	100
Pool 10 (F+J)	Plasma	0	0	0	0	0	0	0	0	0	0	NEG		

1. Pool 1 to 10 contain a 1:1 mixture of the native samples as indicated.
2. 0 = negative band result. 1 = positive band result.

8. Clinical Tests:

Method Comparison: Three sites tested utilized prospectively collected consecutive specimens testing positive on a FDA cleared first-step EIA in the study. 753 specimens were tested on the predicate MarDx *B. burgdorferi* IgG MarBlot Test device as well as the Lyme *B. burgdorferi* (IgG) MarStripe Test

		Predicate IgG WB		
		Positive	Negative	Total
Lyme IgG MarStripe Test	Positive	221	12	233
	Negative	17	503	520
	Total	238	515	753

Positive Agreement: 92.9% (95% CI: 88.6% - 95.7%)
Negative Agreement: 97.7% (95% CI: 95.9% - 98.7%)

The 29 discrepant specimens were tested on two additional commercially available *B. burgdorferi* IgG Western blot methods. Results of the Lyme *B. burgdorferi* (IgG) MarStripe Test were compared to the consensus (2/3 comparator) results. The 12 positives by MarStripe remained positive by consensus testing and the 17 negatives by MarStripe were found to be positives.

		Consensus Result	
		Positive	Negative
Lyme IgG MarStripe Test	Positive	12	0
	Negative	17	0

Sensitivity: 94 well characterized Lyme disease clinical specimens from the above study were tested with the Lyme *B. burgdorferi* (IgG) MarStripe Test. Specimens included samples from early, early disseminated, and late phases of the disease. The sensitivity obtained was compared with that of the predicate device.

Interval	n	Lyme IgG MarStripe Test		Predicate IgG WB	
		positive	%	positive	%
Early Lyme (stage 1)	22	4	18.2	3	13.6
Early disseminated (stage 2)	44	12	27.3	11	25.0
Late Lyme (stage 3)	28	5	17.9	5	17.9
Overall	94	21	19.5	19	20.2

Sensitivity Comparison:

Lyme *B. burgdorferi* (IgG) MarStripe Test: 22.3% (21/94) (95% CI: 14.7%-32.3%)
Predicate device: 20.2% (19/94) (95% CI: 12.9%-30.0%)
Difference in proportion: 2.1%

CDC Panels: Reference panels from the Center for Disease Control and Prevention (Lyme Disease Validation Panel n=10, Lyme Disease Basic Research Panel n=32) were tested on the Lyme *B. burgdorferi* (IgG) MarStripe Test and the predicate device.

Interval	n	Lyme IgG MarStripe Test		Predicate IgG WB	
		positive	%	positive	%
Controls	25	0	0	0	0
Early Lyme (stage 1)	10	1	10	1	10
Early disseminated (stage 2)	3	3	100	3	100
Late Lyme (stage 3)	4	4	100	4	100
Overall	42	7	16.7	7	16.7

Note: The results are presented as a means to convey further information on the performance of this assay with a masked, characterized serum panel. This does not imply an endorsement of the assay by the CDC.

9. **Conclusion:** From the performance data and kit comparison above, it is our conclusion that the Lyme *B. burgdorferi* (IgG) MarStripe Test is substantially equivalent to the B. *burgdorferi* (IgG) MarBlot Strip Test System (K950829) commercially marketed by Trinity Biotech

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VP Regulatory Affairs

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