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

October 23, 2017

TRINITY BIOTECH
KEVIN LAWSON
REGULATORY OFFICER
60 PINEVIEW DR.
BUFFALO NY 14031

Re: K172254
Trade/Device Name: Lyme B. Burgdorferi (igm) Marstripe Test
Regulation Number: 21 CFR 866.3830
Regulation Name: Treponema pallidum treponemal test reagents
Regulatory Class: II
Product Code: LSR
Dated: July 11, 2017
Received: July 26, 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,

Kristian M. Roth -S

For:

Uwe Scherf, M.Sc., 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)*
K172254

Device Name
Lyme *B. burgdorferi* (IgM) MarStripe Test

Indications for Use *(Describe)*
Lyme *B. burgdorferi* (IgM) MarStripe Test is an immunoblot assay for the *in vitro* qualitative detection of human IgM 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.

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

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

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

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

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: 7-24-2017

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

3. **Substantially equivalent to:** MarDx *B. burgdorferi* IgM MarBlot Strip Test System (K951709)

4. **Description of device:** The kit is an immunoblot method to detect IgM antibodies against *B. burgdorferi* antigens. The test kit contains:
   - Nitrocellulose Test Strips with purified *B. burgdorferi* antigens (3) 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 IgM-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 2 (or more) of the 3 test lines are considered positive for specific IgM antibody *to B. burgdorferi*.

5. **Intended Use:** Lyme *B. burgdorferi* (IgM) MarStripe Test is an immunoblot assay for the in vitro qualitative detection of human IgM 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* (IgM) MarStripe Test was compared to a commercially marketed kit by Trinity Biotech the *B. burgdorferi* (IgM) MarBlot Strip Test System (K951709). 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 IgM 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:**
   Precision

Eight specimens were tested by Lyme *B. burgdorferi* (IgM) MarStripe Test in 4 replicates, two runs per day over 12 days for a total of 96 tests for each specimen. Samples were selected based on FDA cleared *B. burgdorferi* ELISA results, including 2 low negative samples, 2 high negative samples, 1 cutoff sample, 1 low positive sample and 2 moderate positive samples. Qualitative agreement was 100% for the low negative, high negative and moderate positive samples. The low positive specimen produced 99.0% positive agreement. The cutoff specimen produced 81.3% positive agreement.

Sample	n=96	p41	p39	p23
1	**Low Negative**			
	Band Type	Neg.	Neg.	Neg.
	Positives	0	0	0
	Negatives	96	96	96
	% Positive	0.0%	0.0%	0.0%
2	**Low Negative**			
	Band Type	Neg.	Neg.	Neg.
	Positives	0	0	3
	Negatives	96	96	93
	% Positive	0.0%	0.0%	3.1%
3	**High Negative**			
	Band Type	Neg.	Neg.	Neg.
	Positives	0	0	0
	Negatives	96	96	96
	% Positive	0.0%	0.0%	0.0%
4	**High Negative**			
	Band Type	Neg.	Neg.	Cut.
	Positives	0	0	3
	Negatives	96	96	93
	% Positive	0.0%	0.0%	3.1%
5	**Cutoff**			
	Band Type	Cut.	Neg.	Wpos.
	Positives	88	0	79
	Negatives	8	96	17
	% Positive	91.7%	0.0%	82.3%
6	**Low Positive**			
	Band Type	Pos.	Neg.	Pos.
	Positives	96	0	96
	Negatives	0	96	0
	% Positive	100.0%	0.0%	100.0%
7	**Moderate Positive**			
	Band Type	Pos.	Neg.	Pos.
	Positives	96	0	96
	Negatives	0	96	0
	% Positive	100.0%	0.0%	100.0%
8	**Moderate Positive**			
	Band Type	Pos.	Pos.	Pos.
	Positives	96	96	96
	Negatives	0	0	0
	% Positive	100.0%	100.0%	100.0%

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

Reproducibility

Eight specimens were tested by Lyme *B. burgdorferi* (IgM) MarStripe Test in 4 replicates, two runs per day over 12 days for a total of 192 tests for each specimen at each of three laboratory sites. Results were read by 2 human operators at each site, equaling a total of 576 read-outs. Samples were selected based on FDA cleared *B. burgdorferi* ELISA results, including 2 low negative samples, 2 high negative samples, 1 cutoff sample, 1 low positive sample and 2 moderate positive samples. Final positive or negative agreement was 100% for both low negative, one high negative and one moderate positive sample. One high negative sample produced 99.7% negative agreement, one low positive and one moderate positive sample produced 99.3% positive agreement. The cutoff sample produced 68.4% positive agreement.

Sample	n=576	p41	p39	p23
1	**Low Negative**			
	Band Type	Neg.	Neg.	Neg.
	Positives	0	0	1
	Negatives	576	576	575
	% Positive	0.0%	0.0%	0.2%
2	**Low Negative**			
	Band Type	Neg.	Neg.	Neg.
	Positives	0	0	26
	Negatives	576	576	550
	% Positive	0.0%	0.0%	4.5%
3	**High Negative**			
	Band Type	Neg.	Neg.	Neg.
	Positives	0	0	0
	Negatives	576	576	576
	% Positive	0.0%	0.0%	0.0%
4	**High Negative**			
	Band Type	Neg.	Neg.	Cut.
	Positives	1	2	58
	Negatives	575	574	518
	% Positive	0.2%	0.3%	10.1%
5	**Cutoff**			
	Band Type	Cut.	Neg.	WPos.
	Positives	442	0	504
	Negatives	134	576	72
	% Positive	76.7%	0.0%	87.5%
6	**Low Positive**			
	Band Type	Pos.	Neg.	Pos.
	Positives	572	0	576
	Negatives	4	576	0
	% Positive	99.3%	0.0%	100.0%
7	**Moderate Positive**			
	Band Type	Pos.	Neg.	Pos.
	Positives	573	0	572
	Negatives	1	574	2
	% Positive	99.8%	0.0%	99.7%
8	**Moderate Positive**			
	Band Type	Pos.	Pos.	Pos.
	Positives	576	572	576
	Negatives	0	4	0
	% Positive	100.0%	99.3%	100.0%

Pos = positive band. Neg = negative band. Wpos = weak positive band. Cut = equivocal band. Note: two replicates of one run are missing due to lack of sample for sample 7.

Analytical Specificity: 220 sera from normal individuals (blood bank donors) representing endemic and non-endemic geographic regions of the United States were tested with Lyme *B. burgdorferi* (IgM) MarStripe Test. Analytical specificity was determined to be 99.5% (95% CI: 97.1% - 100%).

		Normal Individuals
Lyme IgM MarStripe Test	Positive	1
	Negative	219
	Total	220

Cross-reactivity: A total of 246 potentially cross-reactive specimens from individuals with other autoimmune disorders or infectious conditions were tested on Lyme B. burgdorferi (IgM) MarStripe Test. All positive specimens by the Lyme B. burgdorferi (IgM) MarStripe Test were confirmed positive when tested by the predicate IgM Western blot device.

		Positive specimens/reactive antibody lines - n(%)			
Population	n	Positive	p41	p39	p23
E. chafeensis	10	3 (30)	3 (30)	5 (50)	4 (40)
B. microti	10	2 (20)	2 (20)	1 (10)	1 (10)
L. interogans	10	1 (10)	1 (10)	1 (10)	1 (10)
H. pylori	100	1 (1)	1 (1)	1 (1)	1 (1)
Syphilis	10	0 (0)	0 (0)	0 (0)	0 (0)
Influenza	10	0 (0)	0 (0)	1 (10)	0 (0)
Epstein-Barr Virus	22	0 (0)	1 (4.5)	0 (0)	0 (0)
Rocky Mountain Spotted fever	10	0 (0)	0 (0)	0 (0)	0 (0)
Parvovirus B19	9	0 (0)	0 (0)	2 (22.2)	1 (11.1)
Systmatic lupus erythematosus	15	0 (0)	0 (0)	0 (0)	0 (0)
Cytomegalovirus	10	0 (0)	0 (0)	0 (0)	0 (0)
Rheumatoid arthritis	15	0 (0)	0 (0)	0 (0)	0 (0)
Celiac	15	0 (0)	0 (0)	0 (0)	0 (0)
Total	246	7 (2.8)	8 (3.2)	11 (4.4)	8 (3.2)

Interference: Two Lyme IgM negative and three Lyme IgM 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 matrix, 20 pairs of sera/plasma (samples A-J below) were sourced from specimens tested on an FDA cleared Lyme EIA assay. These specimens included 3 Western Blot IgM positives and 17 negatives. These samples were assayed on the Lyme *B. burgdorferi* (IgM) MarStripe Test. Qualitative agreement for all pairs was 100%.

Sample	Type	p41	p39	p23	Result	Band % Agrmt
A	Serum	0	0	0	NEG	100
A	Plasma	0	0	0	NEG	
B	Serum	1	0	1	POS	100
B	Plasma	1	0	1	POS	
C	Serum	0	0	0	NEG	100
C	Plasma	0	0	0	NEG	
D	Serum	0	0	1	NEG	100
D	Plasma	0	0	1	NEG	
E	Serum	1	0	1	POS	100
E	Plasma	1	0	1	POS	
F	Serum	0	0	1	NEG	100
F	Plasma	0	0	1	NEG	
G	Serum	0	0	1	NEG	100
G	Plasma	0	0	1	NEG	
H	Serum	0	0	0	NEG	100
H	Plasma	0	0	0	NEG	
I	Serum	0	0	0	NEG	100
I	Plasma	0	0	0	NEG	
J	Serum	1	0	1	POS	100
J	Plasma	1	0	1	POS	
K	Serum	0	0	0	NEG	100
K	Plasma	0	0	0	NEG	
L	Serum	0	0	0	NEG	100
L	Plasma	0	0	0	NEG	
M	Serum	0	0	0	NEG	100
M	Plasma	0	0	0	NEG	
N	Serum	0	0	0	NEG	100

N	Plasma	0	0	0	NEG	
O	Serum	0	0	0	NEG	100
O	Plasma	0	0	0	NEG	
P	Serum	0	0	1	NEG	100
P	Plasma	0	0	1	NEG	
Q	Serum	0	0	0	NEG	100
Q	Plasma	0	0	0	NEG	
R	Serum	0	0	0	NEG	100
R	Plasma	0	0	0	NEG	
S	Serum	0	0	1	NEG	100
S	Plasma	0	0	1	NEG	
T	Serum	0	0	0	NEG	100
T	Plasma	0	0	0	NEG	

1. 0 = negative band result. 1 = positive band result.

8. Clinical Tests:

Method Comparison: A prospective study of FDA cleared first-step EIA specimens was performed at three geographically distinct study sites. The specimens testing positive (n=676) on a FDA cleared first-step EIA were tested with Lyme B. burgdorferi (IgM) MarStripe Test and an FDA cleared immunoblot. Interpretation of immunoblot results followed the recommended criteria described by the Centers for Disease Control (CDC) and the Second National Conference on Serological Diagnosis of Lyme Disease 22. The results are summarized below.

		Predicate IgM WB		
		Positive	Negative	Total
Lyme IgM MarStripe Test	Positive	302	23	325
	Negative	21	330	351
	Total	323	553	676

Positive % Agreement: 93.5% (95% CI: 90.1% - 95.8%)
Negative % Agreement: 93.5% (95% CI: 90.2% - 95.7%)

Sensitivity: 87 well characterized Lyme disease clinical specimens were tested with the Lyme *B. burgdorferi* (IgM) 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 IgM MarStripe Test		Predicate IgM WB	
		Positive	%	Positive	%
Early Lyme (stage 1)	19	8	42.1	9	47.4
Early disseminated (stage 2)	43	5	11.6	6	14
Late Lyme (stage 3)	25	3	12	2	8
Overall	87	16	18.4	17	19.5

Sensitivity Comparison:
Lyme *B. burgdorferi* (IgM) MarStripe Test: 18.4% (16/87) (95% CI: 11.2% - 28.4%)
Predicate device: 19.5% (17/87) (95% CI: 12.1% - 29.7%)
Difference in proportion: 1.1%

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* (IgM) MarStripe Test and the predicate device.

Interval	n	Lyme IgM MarStripe Test		Predicate IgM WB	
		positive	%	positive	%
Controls	25	0	0	2	8
Early Lyme (stage 1)	10	6	60	6	60
Early disseminated (stage 2)	3	3	100	3	100
Late Lyme (stage 3)	4	1	25	2	50
Overall	42	10	23.8	13	31.0

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* (IgM) MarStripe Test is substantially equivalent to the B. *burgdorferi* (IgM) MarBlot Strip Test System (K951709) commercially marketed by Trinity Biotech

Kevin J. Lawson
VP Regulatory Affairs

60 Pineview Drive ● Buffalo, NY 14228-2120 ● USA
Toll free (800) 537-8378 ● tel. (716) 691-0091 ● fax (716) 691-0466

www.immco.com