October 21, 2020

Arlington Scientific, Inc. (ASI)
David Binks
COO
1840 North Technology Dr.
Springville, Utah 84663

Re: K201438
Trade/Device Name: ASI Automated RPR (rapid plasma reagin) Test for Syphilis, for use on the ASI Evolution Automated Syphilis Analyzer
Regulation Number: 21 CFR 866.3820
Regulation Name: Treponema Pallidum Nontreponemal Test Reagents
Regulatory Class: Class II
Product Code: GMQ,
Dated: May 29, 2020
Received: June 1, 2020

Dear David Binks:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Steven Gitterman, M.D., Ph.D.
Deputy Director
Division of Microbiology Devices
OHT7: Office of In Vitro Diagnostics
and Radiological Health
Office of Product Evaluation and Quality
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K201438

Device Name
ASI Automated RPR Test for Syphilis for Use on the ASI Evolution

Indications for Use *(Describe)*
The ASI Automated RPR (rapid plasma reagin) Test for Syphilis, for use on the ASI Evolution Automated Analyzer, is a qualitative and semiquantitative flocculation test for the detection of nontreponemal antibodies in human serum and plasma to aid in the diagnosis of syphilis. All reactive RPR test samples should be further tested with a treponemal test to determine serological evidence of syphilis infection. The test is intended to be used for in vitro diagnostic testing.

The ASI Automated RPR Test for Syphilis is for professional use only.

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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5.0 510(k) Summary

5.1 Preparation Date: 08/24/2020

Submitted By

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Springville, UT 84663
Phone 801-489-8911 / Fax 801-489-5552

5.2 Trade Name –ASI Automated RPR Test for Syphilis for use on the ASI Evolution

Regulation section: (21 CFR 866.3820) *Treponema pallidum* nontreponemal test reagents

Classification: Class II

Product Code: GMQ

Panel: Microbiology

5.3 Predicate Device(s) – ASI RPR Card Test for Syphilis on the ASI Evolution (K173376, BK170114, and K182391)

Device Similarities and Differences

Item	**ASI Evolution (New Algorithm) (K201438)**	**ASI Evolution (Original Algorithm) (K173376 and K182391)**
Intended Use	The ASI Automated RPR (rapid plasma reagin) Test for Syphilis, for use on the ASI Evolution Automated Analyzer, is a qualitative and semiquantitative flocculation test for the detection of nontreponemal antibodies in human serum and plasma to aid in the diagnosis of syphilis. All reactive RPR test samples should be further tested with a treponemal test to determine serological evidence of syphilis infection. The test is intended to be used for in vitro diagnostic testing. The ASI Automated RPR Test for Syphilis is for professional use only.	The ASI Automated RPR (rapid plasma reagin) Test for Syphilis, for use on the ASI Evolution Automated Syphilis Analyzer, is a qualitative and semi-quantitative nontreponemal flocculation test for the detection of reagin antibodies in human serum and plasma as a screening test for serological evidence of syphilis. All reactive RPR test samples should be further tested with a treponemal test.

		The ASI Automated RPR Test for Syphilis is for professional use only. The test is intended to be used for *in vitro* diagnostic testing and blood donor screening. The ASI Evolution is intended to be used as a fully automated analyzer to objectively interpret the results of the ASI Automated RPR test for Syphilis. The ASI Evolution is designed to provide standardized test interpretation and to provide for storage, retrieval, and transmittal of the test results. It is intended to be acquired, possessed and used only by health care professionals. The ASI Evolution analyzer, in conjunction with the ASI Automated RPR Test for Syphilis is intended to be used for *in vitro* diagnostic testing and blood donor screening.
Technology Instruments	The ASI Evolution is an integrated digital particle analyzer designed to objectively interpret certain agglutination tests manufactured by Arlington Scientific, Inc. (ASI). The ASI Evolution fully automates the sample and reagent handling steps of the test procedure. Laboratory professionals use the ASI Evolution to provide standardized test interpretation using criteria that define reactive and nonreactive agglutination reactions. The ASI Evolution employs a camera to create a highly sensitive and high-resolution image of the agglutination immunoassay. This image is then analyzed by the proprietary software algorithm to interpret the agglutination pattern. The ASI Evolution further provides tools that enable the creation, storage, retrieval and transmittal of the test results.	Same
Technology Reagents	Flocculation Test	Same
Antigen	ASI RPR Carbon Antigen	Same
Reported Results	Reactive, Nonreactive	Same
Interpretation	Automated	Same
Sample Processing	Automated	Same
Reagent Volume used per Sample	110 µl	Same
Sample Type	Serum or Plasma	Same
Controls	Reactive, Weak Reactive, Nonreactive	Same

Test card	48 well plastic test plate	Same
Target Population	Used for *in vitro* diagnostic testing	Same

5.4 Device Description – The ASI Evolution is an integrated digital particle analyzer designed to objectively interpret certain slide agglutination tests manufactured by Arlington Scientific, Inc. (ASI). The ASI Evolution fully automates the sample and reagent handling steps of the test procedure. Qualitative and semiquantitative tests are performed by laboratory professionals who use the ASI Evolution to provide standardized test interpretation using criteria that define reactive and nonreactive agglutination reactions.

The ASI Evolution employs a camera that uses light reflectance to create a highly sensitive and high-resolution image of the agglutination immunoassay. This image is then analyzed by the proprietary software algorithm to interpret the agglutination pattern.

The ASI Evolution further provides tools that enable the creation, storage, retrieval and transmittal of the test results.

The ASI Automated RPR Test for Syphilis reagents include the following:

CARBON ANTIGEN - 0.003% cardiolipin, 0.020–0.022% lecithin, 0.09% cholesterol, charcoal (activated) as visual enhancer, phosphate buffer, 0.1% sodium azide as preservative and stabilizers.

CONTROLS (REACTIVE, WEAK REACTIVE, NONREACTIVE) - Human serum or defibrinated plasma (liquid), with 0.1% sodium azide as preservative.

Reagents have two-year expiration dating from date of manufacture. The specific expiration date is located on the label on the vial.

Intended Use –

The ASI Automated RPR (rapid plasma reagin) Test for Syphilis, for use on the ASI Evolution Automated Analyzer, is a qualitative and semiquantitative flocculation test for the detection of nontreponemal antibodies in human serum and plasma to aid in the diagnosis of syphilis. All reactive RPR test samples should be further tested with a treponemal test to determine serological evidence of syphilis infection. The test is intended to be used for in vitro diagnostic testing.

The ASI Automated RPR Test for Syphilis is for professional use only.

Performance Data – A comparison of the digital interpretation of the results from the ASI Evolution using the original interpretation algorithm (K173376, BK170114, and K182391) to establish substantial equivalence to the interpretation made by the ASI Evolution using the new interpretation algorithm was conducted.

The ASI Evolution was evaluated for equivalence, in its pattern of reactivity using a total of 1,762 individual retrospective samples, with identifiers removed, that had been collected from different Departments of Public Health Labs and Blood Banks. Reactive, Weak Reactive and Nonreactive controls were run on each day of testing.

Retrospective Serum Sample Testing – 872 Samples

		ASI Evolution Original Algorithm	
		Reactive	Nonreactive
ASI Evolution New Algorithm	Reactive	91	6
	Nonreactive	0	775

Note: The six discordant results were investigated and tested with a treponemal test and found to be reactive.

Serum positive agreement is calculated as:

91/(91 + 0) = 100%
95% CI = 96.03% - 100%

Serum negative agreement is calculated as:

775/(775 + 6) = 99.23%
95% CI = 98.34% - 99.72%

Serum samples were from both SST and Red Top tubes.

Retrospective Plasma Sample Testing – 890 Samples

		ASI Evolution Original Algorithm	
		Reactive	Nonreactive
ASI Evolution New Algorithm	Reactive	119	1
	Nonreactive	5	765

Note: The six discordant results were investigated and the sample that was called reactive by the new algorithm and nonreactive by the original algorithm was tested with a treponemal test and found to be nonreactive. The five samples that were called nonreactive by the new algorithm and reactive by the original algorithm had bubbles or artifacts in the test well.

Total Plasma positive agreement is calculated as:

119/(119 + 5) = 95.97%

95% CI = 90.91% - 98.27%

Sodium Citrate positive agreement is calculated as:

55/(55 + 4) = 93.22%
95% CI = 83.54% - 98.12%

EDTA positive agreement is calculated as:

64/(64 + 1) = 98.46%
95% CI = 91.72% - 99.96%

Total Plasma negative agreement is calculated as:

765/(765 + 1) = 99.87%
95% CI = 99.27% - 100.00%

Sodium Citrate negative agreement is calculated as:

465/(465 + 1) = 99.79%
95% CI = 98.81% - 99.99%

EDTA negative agreement is calculated as:

300/(300 + 0) = 100%
95% CI = 98.78% - 100%

Pregnant Women Testing

		ASI RPR Card Test for Syphilis on the ASiManager-AT Result	
		Reactive	Nonreactive
ASI Automated RPR Test for Syphilis on the ASI Evolution Result	Reactive	30	0
	Nonreactive	0	250

Conclusion:

The positive and negative percent agreement for the two algorithms demonstrate that they have a very similar performance.

Reproducibility

Reproducibility testing was conducted. The testing consisted of:

- Testing seven (7) samples
  - 2 - RPR nonreactive samples
  - 2 – RPR reactive 1:2 titered samples
  - 1 – RPR reactive 1:4 titered sample
  - 1 - RPR reactive 1:8 titered sample
  - 1 – RPR reactive 1:16 titered sample
- Each sample was run in duplicate within the panel.
- Each sample was tested each day for five non-consecutive days by an operator with experience in performing the ASI Automated RPR Test for Syphilis
- Each sample was tested a second time on each of the days referenced above separated by approximately 2 hours.

RPR				
Sample	***Sample #***	***N***	***Expected Result***	***95% Confidence Interval***
RPR nonreactive	10159A	60	100% (60/60)	94.04 - 100
RPR nonreactive	06127	60	100% (60/60)	94.04 - 100
RPR reactive 1:2	10159D	60	100% (60/60)	94.04 - 100
RPR reactive 1:2	W9P19R	60	100% (60/60)	94.04 - 100
RPR reactive 1:4	10159C	60	100% (60/60)	94.04 - 100
RPR reactive 1:8	10159E	60	100% (60/60)	94.04 - 100
RPR reactive 1:16	R0B03R	60	100% (60/60)	94.04 - 100

The data shows a very high degree of reproducibility.

End-point Titer Testing

A total of 9 samples with identifiers removed were tested to determine patterns of reactivity using the semiquantitative test procedure on the ASI Evolution with the new interpretation algorithm with the reagents of the ASI Automated RPR Test for Syphilis. There were no errors with the instrument during the testing.

The nine samples were made up of prospective control serum and serum samples of known reactivity. All samples had been tested by the manual interpretation method prior to testing. The expected results were established by this testing. These specimens were tested with ASI carbon antigen (CA9P02RRD). The samples were as follows:

Sample ID	Sample Type	Titer
06127	Normal Human Serum	Nonreactive (NR)
10159A	Nonreactive Control	Nonreactive (NR)
10159E	Human Serum	Reactive (1:8)
10159D	Human Serum	Reactive (1:2)
W9P19R	Weak Reactive Control	Reactive (1:2)
R0B03R	Reactive Control	Reactive (1:8)
01140	Human Serum	Reactive (1:64)
10159	Human Serum	Reactive (1:128)
10189C	Human Serum	Reactive (1:256)

The nine samples were tested in eight replicates on ten different days. Not all samples were tested on the same day. Each sample set of eight replicates were tested ten times giving a total of 80 data points for each sample. The line item data is included with this submission as a separate document. An acceptable result is within +/- 1 titer of the expected result. Nonreactive samples must be nonreactive. The results of the semiquantitative analysis samples are shown in tables below:

Titration Sample Testing

Sample ID	06127	10159A	10159E	10159D	W9P19R	R0B03R	01140	10159	10189C
Expected Result	NR	NR	1:8	1:2	1:2	1:8	1:64	1:128	1:256
Run									
1	8/8	8/8	8/8	8/8	8/8	8/8	8/8	8/8	8/8
2	8/8	8/8	8/8	8/8	8/8	8/8	8/8	8/8	8/8
3	8/8	8/8	8/8	8/8	8/8	8/8	8/8	8/8	8/8
4	8/8	8/8	8/8	8/8	8/8	8/8	8/8	8/8	8/8
5	8/8	8/8	8/8	8/8	8/8	8/8	8/8	8/8	8/8
6	8/8	8/8	8/8	8/8	8/8	8/8	8/8	8/8	8/8
7	8/8	8/8	8/8	8/8	8/8	8/8	8/8	8/8	8/8
8	8/8	8/8	8/8	8/8	8/8	8/8	8/8	8/8	8/8
9	8/8	8/8	8/8	8/8	8/8	8/8	8/8	8/8	8/8
10	8/8	8/8	8/8	8/8	8/8	8/8	8/8	8/8	8/8
Total	80/80	80/80	80/80	80/80	80/80	80/80	80/80	80/80	80/80

All titration samples were within the +/- one titer.

RPR Endpoint Manual Testing			RPR Endpoint Titer New Algorithm								
	Nonreactive	1:1 (Neat)	1:2	1:4	1:8	1:16	1:32	1:64	1:128	1:256	1:512
Nonreactive	160										
1:2			101	59							
1:8				20	120	20					
1:64							17	46	17		
1:128								26	53	1	
1:256									35	40	5