

**K182391 ASI Automated ASI RPR Test for Syphilis on the ASI Evolution**

Nov 30, 2018  
87 days to decision

K182391 · Product code: **GMQ** · Microbiology  
Source: <https://www.510kdatabase.net/k182391/>

**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Antigens, Nontreponemal, All (GMQ)
Date received	Sep 4, 2018
Decision date	Nov 30, 2018
Days to decision	87 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Arlington Scientific, Inc. (Asi)</b>
Location	Springville, UT, US
Contact	David Binks
510(k) history	3 submissions · 3 cleared · 2018-2020

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)

Device record: <https://www.510kdatabase.net/k182391/>. Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).

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