

**K192046 LIAISON XL Zika Capture IgM II and LIAISON XL Zika Capture IgM II Control Set**Oct 28, 2019  
89 days to decisionK192046 · Product code: **QFO** · Microbiology  
Source: <https://www.510kdatabase.net/k192046/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Zika Virus Serological Reagents (QFO)
Date received	Jul 31, 2019
Decision date	Oct 28, 2019
Days to decision	89 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>DiaSorin, Inc.</b>
Location	Ellicott City, MD, US
Contact	John C. Walter
510(k) history	71 submissions · 70 cleared · 1998-2026

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**510k Database** - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k192046/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated June 28, 2026