

K191578 ADVIA Centaur Zika test, ADVIA Centaur Zika Ab (100 tests), ADVIA Centaur Zika IgM (50 tests), ADVIA Centaur Zika Ab Quality Control, ADVIA Centaur Zika IgM Quality ControlJul 17, 2019
33 days to decisionK191578 · Product code: **QFO** · Microbiology
Source: <https://www.510kdatabase.net/k191578/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Zika Virus Serological Reagents (QFO)
Date received	Jun 14, 2019
Decision date	Jul 17, 2019
Days to decision	33 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Siemens Healthcare Diagnostics, Inc.
Location	New York, NY, US
Contact	Matthew Gee
Website	https://www.siemens-healthineers.com
510(k) history	152 submissions · 151 cleared · 2008-2026

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