

**K200506 DPP Zika IgM System, DPP Zika IgM System Control Pack, and DPP Micro Reader**Jun 3, 2020  
93 days to decisionK200506 · Product code: **QFO** · Microbiology  
Source: <https://www.510kdatabase.net/k200506/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Zika Virus Serological Reagents (QFO)
Date received	Mar 2, 2020
Decision date	Jun 3, 2020
Days to decision	93 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Chembio Diagnostic Systems</b>
Location	Medford, NY, US
Contact	Louise Muscat Sigismondi
510(k) history	1 submissions · 1 cleared · 2020-2020

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