

**K193047 N Latex FLC kappa, N Latex FLC lambda**Jul 14, 2021  
621 days to decisionK193047 · Product code: **DFH** · Immunology  
Source: <https://www.510kdatabase.net/k193047/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Kappa, Antigen, Antiserum, Control (DFH)
Date received	Nov 1, 2019
Decision date	Jul 14, 2021
Days to decision	621 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Siemens Healthcare Diagnostics Products GmbH</b>
Location	Marburg, DE
Contact	Christine Perkins
510(k) history	19 submissions · 18 cleared · 2016-2024

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