

K212379 N Latex FLC kappa, N Latex FLC lambdaMar 2, 2022
212 days to decisionK212379 · Product code: **DFH** · Immunology
Source: <https://www.510kdatabase.net/k212379/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Kappa, Antigen, Antiserum, Control (DFH)
Date received	Aug 2, 2021
Decision date	Mar 2, 2022
Days to decision	212 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Siemens Healthcare Diagnostics Products GmbH
Location	Marburg, DE
Contact	Martina Pfeiff
510(k) history	19 submissions · 18 cleared · 2016-2024

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