

K201496 N Latex FLC kappa, N Latex FLC lambdaOct 29, 2021
511 days to decisionK201496 · Product code: **DFH** · Immunology
Source: <https://www.510kdatabase.net/k201496/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Kappa, Antigen, Antiserum, Control (DFH)
Date received	Jun 5, 2020
Decision date	Oct 29, 2021
Days to decision	511 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k201496/> Data sourced from FDA 510(k) public records (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. - Generated May 26, 2026