

**K171742 N Latex FLC kappa assay, N Latex FLC Lambda assay,
N FLC Standard SL, N FLC Control SL1 & SL2**Nov 17, 2017
158 days to decisionK171742 · Product code: **DFH** · Immunology
Source: <https://www.510kdatabase.net/k171742/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Kappa, Antigen, Antiserum, Control (DFH)
Date received	Jun 12, 2017
Decision date	Nov 17, 2017
Days to decision	158 days
Third-party review	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

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