

K190879 N Latex FLC kappa, N Latex FLC lambdaMay 3, 2019
29 days to decisionK190879 · Product code: **DFH** · Immunology
Source: <https://www.510kdatabase.net/k190879/>**SUBMISSION DETAILS**

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|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Special |
| Device classification | Kappa, Antigen, Antiserum, Control (DFH) |
| Date received | Apr 4, 2019 |
| Decision date | May 3, 2019 |
| Days to decision | 29 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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