

K110303 STRATUS CS ACUTE CARE D-DIMERMay 16, 2011
104 days to decisionK110303 · Product code: **DAP** · Hematology
Source: <https://www.510kdatabase.net/k110303/>**SUBMISSION DETAILS**

| | |
|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Fibrinogen And Fibrin Split Products, Antigen, Antiserum, Control (DAP) |
| Date received | Feb 1, 2011 |
| Decision date | May 16, 2011 |
| Days to decision | 104 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Siemens Healthcare Diagnostics |
| Location | Newark, DE, US |
| Contact | KATHLEEN ANN DRAY-LYONS |
| 510(k) history | 92 submissions · 92 cleared · 2008-2025 |

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