

**K091216 CLINITEK STATUS+ANALYZER AND CLINITEK
STATUS CONNECT SYSTEM, MODELS 1780, 1797**Oct 9, 2009
165 days to decisionK091216 · Product code: JIL · Chemistry
Source: <https://www.510kdatabase.net/k091216/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Method, Enzymatic, Glucose (urinary, Non-quantitative) (JIL)
Date received	Apr 27, 2009
Decision date	Oct 9, 2009
Days to decision	165 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Siemens Healthcare Diagnostics
Location	Newark, DE, US
Contact	NOOR MALKI
510(k) history	92 submissions · 92 cleared · 2008-2025

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k091216/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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