

K133128 IMMULITE 2000Oct 22, 2013
22 days to decisionK133128 · Product code: **JJX** · Chemistry
Source: <https://www.510kdatabase.net/k133128/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Single (specified) Analyte Controls (assayed And Unassayed) (JJX)
Date received	Sep 30, 2013
Decision date	Oct 22, 2013
Days to decision	22 days
Third-party review	No
Summary / Statement	Summary
Other names	HCG CALIBRATION VERIFICATION MATERIAL, INSULIN CALIBRATION VERIFICATION MATERIAL, PYRILINKS-D CALIBRATION

APPLICANT

Company	Siemens Healthcare Diagnostics, Inc.
Location	New York, NY, US
Contact	Asha Gartland
Website	https://www.siemens-healthineers.com
510(k) history	152 submissions · 151 cleared · 2008-2026

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k133128/> 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 14, 2026