

**K133816 IMMULITE 2000 FREE PSA CALIBRATION
VERIFICATION MATERIAL**Jun 24, 2014
190 days to decisionK133816 · Product code: **JJX** · Immunology
Source: <https://www.510kdatabase.net/k133816/>**SUBMISSION DETAILS**

| | |
|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Single (specified) Analyte Controls (assayed And Unassayed) (JJX) |
| Date received | Dec 16, 2013 |
| Decision date | Jun 24, 2014 |
| Days to decision | 190 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

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

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