

**K132739 IMMULITE 2000 AFP, BR-MA, AND OM-MA
CALIBRATION VERIFICATION MATERIAL**Jan 14, 2014
133 days to decisionK132739 · Product code: **JJX** · Immunology
Source: <https://www.510kdatabase.net/k132739/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Single (specified) Analyte Controls (assayed And Unassayed) (JJX)
Date received	Sep 3, 2013
Decision date	Jan 14, 2014
Days to decision	133 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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