

K143373 IMMULITE® 2000 Calcitonin Calibration Verification Material , IMMULITE® 2000 Prostatic Acid Phosphatase (PAP) Calibration Verification MaterialFeb 26, 2015
93 days to decisionK143373 · Product code: **JJX** · Chemistry
Source: <https://www.510kdatabase.net/k143373/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Single (specified) Analyte Controls (assayed And Unassayed) (JJX)
Date received	Nov 25, 2014
Decision date	Feb 26, 2015
Days to decision	93 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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