

**K143636 IMMULITE 2000 Androstenedione Calibration  
Verification Material, IMMULITE 2000 Troponin I Calibration  
Verification Material**Feb 25, 2015  
65 days to decisionK143636 · Product code: **JJX** · Chemistry  
Source: <https://www.510kdatabase.net/k143636/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Single (specified) Analyte Controls (assayed And Unassayed) (JJX)
Date received	Dec 22, 2014
Decision date	Feb 25, 2015
Days to decision	65 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Siemens Healthcare Diagnostics, Inc.</b>
Location	New York, NY, US
Contact	Donna Velasquez
Website	<a href="https://www.siemens-healthineers.com">https://www.siemens-healthineers.com</a>
510(k) history	152 submissions · 151 cleared · 2008-2026

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k143636/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated May 14, 2026