

K162538 ADVIA Centaur Insulin (IRI) Master Curve Material (MCM), ADVIA Centaur (IRI) CalibratorNov 17, 2016
66 days to decisionK162538 · Product code: JIT · Chemistry
Source: <https://www.510kdatabase.net/k162538/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Calibrator, Secondary (JIT)
Date received	Sep 12, 2016
Decision date	Nov 17, 2016
Days to decision	66 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Siemens Healthcare Diagnostics
Location	Newark, DE, US
Contact	SUSAN FERRIN
510(k) history	92 submissions · 92 cleared · 2008-2025

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k162538/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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